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Paper 84
Entered: May 29, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

IPR2018-01678[1]
Patent 8,992,486 B2

Before HYUN J. JUNG, BART A. GERSTENBLITH, and JAMES A. TARTAL, *Administrative Patent Judges.*

JUNG, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Petitioner's Motion to Exclude
35 U.S.C. § 318(a)

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[1] Pfizer Inc., who filed a petition in IPR2019-00980, has been joined as petitioner in this proceeding. Paper 41.

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Mylan Pharmaceuticals Inc. and Pfizer Inc. (collectively, "Petitioner") have shown by a preponderance of the evidence that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of U.S. Patent No. 8,992,486 B2 (Ex. 1003, "the '486 patent") are unpatentable. We also deny Petitioner's Motion to Exclude.

A. Background and Summary

Mylan Pharmaceuticals Inc. ("Mylan") filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the '486 patent. Sanofi-Aventis Deutschland GmbH ("Patent Owner") filed a Preliminary Response (Paper 10). Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of the '486 patent. Paper 20 ("Dec. to Inst."). In particular, we instituted review of all challenged claims on all presented challenges. Dec. to Inst. 2, 24, 27, 31–33.

Pfizer Inc. ("Pfizer") filed a substantively identical petition (*Pfizer Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-00980, Paper 2 (PTAB May 2, 2019) (Petition)) and a motion for joinder seeking to join this proceeding (*Pfizer*, Paper 3), which we granted. Paper 41.

After institution, Patent Owner filed a Response (Paper 31, "PO Resp."), to which Petitioner filed a Reply (Paper 46, "Pet. Reply"), and Patent Owner thereafter filed a Sur-reply (Paper 56, "PO Sur-reply"). Petitioner also filed a motion to exclude (Paper 64, "Mot."), and Patent Owner filed an opposition to the motion to exclude (Paper 65, "Opp."), to which Petitioner filed a reply (Paper 70, "Mot. Reply"). An oral hearing in

this proceeding was held on January 15, 2020; a transcript of the hearing is included in the record (Paper 78, "Tr.").

B. Real Parties in Interest

Mylan indicates that Mylan Pharmaceuticals Inc., Mylan Inc., Mylan GmbH (Mylan N.V. subsidiaries), Biocon Research Ltd., Biocon Ltd., and Becton, Dickinson and Company are real parties in interest. Pet. 1; Paper 8, 2. Pfizer indicates that Pfizer and Hospira, Inc. are real parties in interest. *Pfizer*, Paper 2 at 1. Patent Owner indicates that Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie are real parties in interest. Paper 5, 2; Paper 9, 2; Paper 25, 2; Paper 51, 2.

C. Related Matters

The parties indicate that the '486 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812-RGA-MPT (D. Del.); and *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113-RGA-MPT (D. Del.). Pet. 1; Paper 5, 2; Paper 8, 2; Paper 9, 2; Paper 25, 2; Paper 51, 2; Exs. 1029, 1030.

The '486 patent is also challenged in IPR2018-01677, IPR2018-01679, IPR2019-00122, IPR2019-00980, IPR2019-00981, and IPR2019-00982. Pet. 2; Paper 5, 3; Paper 8, 2; Paper 9, 3; Paper 25, 3–4; Paper 51, 2–3. Petitioner's motion to dismiss its petition in IPR2018-01677 was granted.

Related patents are challenged in IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, IPR2019-00977, IPR2019-00978, IPR2019-00979, IPR2019-00987, IPR2019-01022, and IPR2019-01023. Pet. 2; Paper 5, 2–3; Paper 8, 2–3; Paper 9, 2–3; Paper 25, 2–4; Paper 51, 1–3.

D. The '486 Patent (Ex. 1003)

The '486 patent issued March 31, 2015, from an application filed June 4, 2013, which is the latest application in a series of continuation applications, the first of which was filed on March 2, 2004. Ex. 1003, codes (22), (45), (63), 1:6–12. The '486 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at code (30), 1:12–14.

The '486 patent "relates to pen-type injectors . . . where a user may set the dose." *Id.* at 1:20–24. Figures 1 and 2 of the '486 patent are reproduced below.

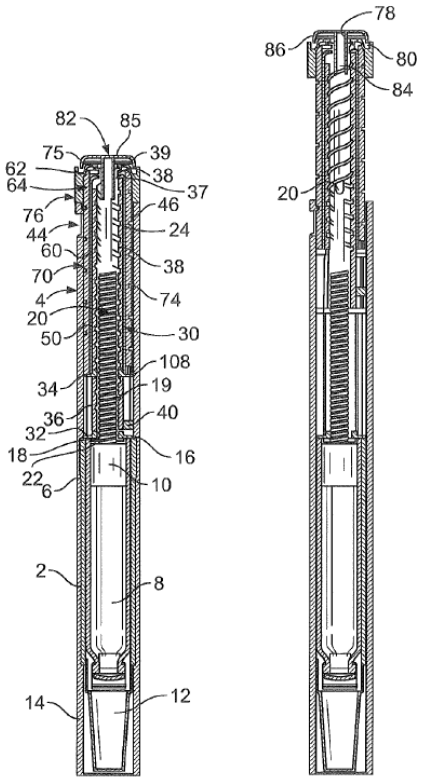

FIG. 1 FIG. 2

Figure 1 "shows a sectional view of a pen-type injector . . . in a first, cartridge full position," and Figure 2 "shows a sectional view of the pen-type injector . . . in a second, maximum first dose dialed, position." Ex. 1003, 2:53–57. The injector includes first cartridge retaining part 2 and main

housing part 4.[2] *Id.* at 3:27–28. Insert 16 is at a first end of housing part 4 and is fixed rotationally and axially to main housing 4. *Id.* at 3:49–51. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:51–53, 3:57–59. Piston rod 20 includes first thread 19 that engages threaded circular opening 18. *Id.* at 3:56.

Piston rod 20 also includes pressure foot 22 that abuts piston 10 of cartridge 8. *Id.* at 3:36–37, 3:59–60. Drive sleeve 30 extends about piston rod 20, and second thread 24 of piston rod 20 engages internal helical groove 38 of drive sleeve 30. *Id.* at 3:61–62, 4:4, 4:13–14.

Clutch or clutch means 60 is disposed about drive sleeve 30 adjacent its second end. *Id.* at 4:33–35, 4:49–50. Clutch 60 is keyed to drive sleeve 30 by splines to prevent relative rotation between clutch 60 and drive sleeve 30. *Id.* at 4:60–62. Clutch 60 also has teeth 66 that engage dose-dial sleeve 70. *See id.* at 4:50–52.

Dose-dial sleeve 70 is outside of clutch 60 but within main housing 4. *Id.* at 5:3–5. Dose-dial sleeve 70 has helical groove 74 on its outer surface, and helical rib 46 of housing 4 is seated in helical groove 70. *Id.* at 5:5–6, 5:9–11. Dose-dial grip 76 is disposed about and secured to the second end of dose-dial sleeve 70. *Id.* at 5:24–25, 5:27–28.

A user rotates dose-dial grip 76 to set a dose and to cause dose-dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of main housing 4. Ex. 1003, 5:50–53, 5:61–65, Fig. 9. The dose can be reduced by turning dose-dial grip 76 in the opposite direction. *Id.* at 6:19–20, Fig. 10. The user then presses button 82, which causes clutch 60 to disengage from

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[2] The ’486 patent refers to “second main housing part 4” and “main housing 4” interchangeably. *Compare* Ex. 1003, 3:28 (“second main housing part 4”), *with id.* at 3:30 (“main housing 4”).

dose-dial sleeve 70 so that clutch 60 moves axially and dose-dial sleeve 70 rotates back into main housing 4. *Id.* at 6:28–35, 6:38–40, Fig. 11. Drive sleeve 30 also moves axially and causes piston rod 20 to rotate through threaded opening 18 to dispense medicine from cartridge 8. *Id.* at 6:45–47.

E. Illustrative Claim

The '486 patent has 57 claims, of which Petitioner challenges claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 in this proceeding. Of those, claim 1, reproduced below, is the only independent claim.

> 1. A housing part for a medication dispensing apparatus, said housing part comprising:
>
> a main housing, said main housing extending from a distal end to a proximal end;
>
> a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;
>
> a dose knob disposed near a proximal end of said dose dial sleeve;
>
> a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;
>
> a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and,
>
> a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob,
>
> wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Ex. 1003, 6:59–7:12.

F. Evidence

Petitioner identifies the following references as prior art in the asserted grounds of unpatentability:

U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014, "Steenfeldt-Jensen"); and

U.S. Patent Application Publication No. US 2002/0052578 A1, published May 2, 2002 (Ex. 1015, "Moller").

Petitioner provides a Declaration (Ex. 1011) and Reply Declaration (Ex. 1095) of Karl R. Leinsing, MSME, PE. Patent Owner provides a Declaration of Alexander Slocum, Ph.D. Ex. 2107. Deposition transcripts were filed for Mr. Leinsing (Exs. 2163, 2164, 2316) and Dr. Slocum (Exs. 1053, 1054).

Primarily in support of objective indicia of nonobviousness, Patent Owner provides declarations from Henry G. Grabowski, Ph.D. (Ex. 2109) and Dr. Robin S. Goland (Ex. 2111). *See* Ex. 2109 ¶ 7 (stating that "I have been retained by counsel for Sanofi to opine on the commercial success of Lantus® SoloSTAR®"); Ex. 2111 ¶ 14 (stating in "Summary of Opinions" that "it is my opinion that patients who require insulin or insulin analog therapy need an easy-to-use injection pen device").

In response, Petitioner provides declarations from Dr. William C. Biggs (Ex. 1048[3]) and DeForest McDuff, Ph.D. (Ex. 1060). *See* Ex. 1048 ¶ 16 (stating that "[m]y opinions are directed principally to long-felt, unmet need arguments"); Ex. 1060 ¶ 6 (stating that the scope of work is to review and respond to the Grabowski declaration regarding commercial success). Deposition transcripts were filed for Prof. Grabowski (Ex. 1055), Dr. Goland (Ex. 1056), Dr. Biggs (Ex. 2317), and Dr. McDuff (Ex. 2318).

[3] Petitioner filed a corrected version of Dr. Biggs's declaration as Exhibit 1048, but "Exhibit 1049" appears on the pages of the declaration.

Patent Owner submits Observations from Mr. Leinsing's cross-examination in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.). Paper 68. The cross-examination is filed as Exhibit 2227. Petitioner submits Observations from the testimony of Dr. Slocum from the same district court case. Paper 69. The testimony is filed as Exhibit 1115. Both parties also filed Responses to each other's Observations. Papers 71, 72.

G. Asserted Grounds

Petitioner asserts that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 would have been unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–6, 12–18, 20, 23, 26–30, 32, 33, 36, 38–40	103(a)[4]	Steenfeldt-Jensen
1–6, 12–18, 20, 23, 26–30, 32, 33, 36, 38–40	103(a)	Moller, Steenfeldt-Jensen

II. ANALYSIS

A. Legal Standards

In an *inter partes* review, Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in its challenges,

[4] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the challenged claims have an effective filing date before this date, the pre-AIA version of § 103 applies.

Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d).

The U.S. Supreme Court set forth the framework for applying the statutory language of 35 U.S.C. § 103 in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

As explained by the Supreme Court in *KSR International Co. v. Teleflex Inc.*:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")).

"Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact." *WBIP, LLC v.*

Kohler Co., 829 F.3d 1317, 1327 (Fed. Cir. 2016). "[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan 'would have had a reasonable expectation of success from doing so.'" *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

As discussed below, the parties' disputes are related to the scope and content of the prior art, differences between claims 1, 30, and 32 and the asserted prior art, and objective evidence of nonobviousness.

After reviewing the complete record, we conclude that Petitioner has shown by a preponderance of the evidence that Steenfeldt-Jensen teaches or suggests each limitation of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40; that a person of ordinary skill in the art would have had a reason to modify Steenfeldt-Jensen; that a person of ordinary skill in the art would have had a reasonable expectation of success in modifying Steenfeldt-Jensen; and that nexus has not been demonstrated sufficiently for the asserted objective indicia of nonobviousness.

B. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art "had at least a bachelor's degree in mechanical engineering, or an equivalent degree, plus three-years' experience" and "understood the basics of medical-device design and manufacturing, and mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices." Pet. 13–14 (citing Ex. 1011 ¶ 106). In our Decision to Institute, we preliminarily adopted Petitioner's unopposed proposal. Dec. to Inst. 17.

Patent Owner contends that a person of ordinary skill in the art would have understood "the mechanical elements (e.g., lead screws, clutches, gears) used in drug injection delivery devices as well as the principles governing the interactions of such mechanical elements, and further [would have understood] the basics of device design and manufacturing" and would have had "a bachelor's degree in mechanical engineering or an equivalent degree." PO Resp. 14 (citing Ex. 2107 ¶ 102). Patent Owner also states that "the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments made below." *Id.* at 15.

In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation and internal quotation marks omitted).

Based on the full record before us, we see no reason to disturb our preliminary finding regarding the level of ordinary skill in the art. Accordingly, we maintain and reaffirm that one of ordinary skill in the art "would have had at least a bachelor's degree in mechanical engineering, or an equivalent degree" and "would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices." Dec. to Inst. 16–17 (quoting Pet. 13–14). This level of skill in the art is consistent with the disclosure of the '486 patent and the prior art of record.

We agree with the parties that any differences in the parties' proposals do not affect their arguments and, thus, would not affect our analysis. PO

Resp. 15; *see also* Tr. 8:14–24 (Petitioner's counsel agreeing that any differences in the parties' proposals would not affect Petitioner's analysis).

C. Claim Construction

In this *inter partes* review, claim terms are interpreted according to their broadest reasonable construction in light of the Specification of the '486 patent. 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).[5]

Petitioner states that "[c]laims should be given their ordinary and customary meaning, consistent with the specification, as a [person of ordinary skill in the art] understood them" and that the "grounds rely on the ordinary and customary meaning." Pet. 14, 16. Petitioner provides Patent Owner's proposed interpretations of "driver," "main housing," "piston rod," "thread/threaded/threading," "tubular clutch," "clicker," and "insert" that were proffered in related litigation. *Id.* at 14–15 (citing Ex. 1019, 21, 23, 25, 27, 30–32). Petitioner also notes that it proffered means-plus-function interpretations for "clutch," "clicker," and "insert" in related litigation. *Id.* at 15 (citing Ex. 1028, 101–106, 112–116). Petitioner proposes the same interpretations in this proceeding, if they are applicable. Pet. 15–16 (citing Ex. 1003, Abstract, 2:1–3, 2:16–35, 4:33–67, 5:1–6, 5:44–60, 6:16–43,

[5] On October 11, 2018, the Office revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)). This rule change does not apply to this proceeding. *Id.*; *see* Paper 6, 1 (according a filing date of September 10, 2018, to the Petition).

Figs. 1, 3–11; Ex. 1028, 104, 106, 112–116). Petitioner states that the "grounds . . . also address the 'clutch,' 'clicker,' and 'insert' limitations as means-plus-function limitations." *Id.* at 16.

Patent Owner proposes interpreting "main housing" to mean "an ***exterior*** unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components" with support from a related patent and the '486 patent's Specification. PO Resp. 9–13. Patent Owner argues that its proposed interpretation of "'main housing is dispositive of Ground 2 because Møller does not disclose a 'dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing,' as properly construed." *Id.* at 13.

For the reasons discussed below, Petitioner persuades us by a preponderance of the evidence that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 are unpatentable over Steenfeldt-Jensen. We, therefore, do not reach the challenge of the same claims as unpatentable over Moller in combination with Steenfeldt-Jensen. Accordingly, because Patent Owner's proposed interpretation is primarily directed at the Moller in combination with Steenfeldt-Jensen challenge, we determine that no claim terms require express construction. *Vivid Techs.*, 200 F.3d at 803.

D. Scope and Content of the Asserted Prior Art

1. Steenfeldt-Jensen (Ex. 1014)

Steenfeldt-Jensen "relates to injection syringes of the kind apportioning set doses of medicine from a cartridge." Ex. 1014, 1:12–13. Figures 16 and 17 of Steenfeldt-Jensen are reproduced below.

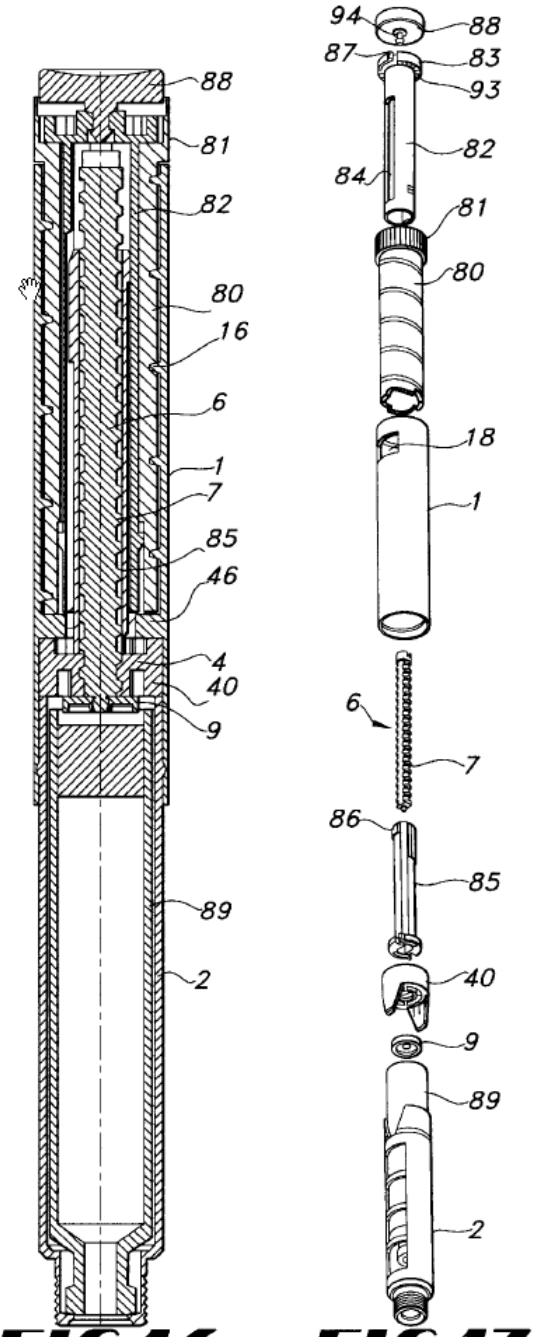

FIG 16 FIG 17

Figures 16 and 17 show side sectional views of a syringe. Ex. 1014, 5:25–28. The syringe of Steenfeldt-Jensen includes tubular housing 1 that is partitioned so that a first division has ampoule holder 2. *Id.* at 5:38–40. Ampoule holder 2 has a central bore with thread 5 that engages external thread 7 of piston rod 6. Ex. 1014, 5:55–58. Driver tube 85 is disposed

about piston rod 6. *See id.* at Figs. 15–17. "The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section" so that "rotation is transmitted" and "the piston rod is allowed to move longitudinally through the driver tube." *Id.* at 11:15–19.

Within housing 1 is scale drum 80, and scale drum 80 has on its outer wall a helical track that is engaged with a helical rib on the inner wall of housing 1. *Id.* at 11:20–22. One end of scale drum 80 has a larger diameter so as to form dose setting button 81. *Id.* at 11:22–24. Bushing 82 fits within scale drum 82 and over driver tube 85. *Id.* at 11:26–29. Bushing 82 is coupled to driver tube 85 so that both can rotate but not longitudinally move. *Id.* at 11:30–33. Injection button 88 is rotatably mounted at an end of bushing 82. *Id.* at 11:49–51.

A dose is set by rotating dose setting button 81, which causes scale drum 80 to rotate out of housing 1. *Id.* at 11:52–55. Injection button 88 is pressed to inject the set dose. *Id.* at 12:4–5. Scale drum 80 is pressed back into housing 1. *Id.* at 12:9–10. Dose setting button 81 rotates because of the engagement between the helical track of scale drum 80 and the helical rib of housing 1. *Id.* at 12:6–9. Piston rod 6 is screwed into ampoule 89 in ampoule holder 2. *Id.* at 12:12–13.

2. Moller (Ex. 1015)

Moller "relates to syringes by which a dose can be set by rotating a dose setting member and by which an injection button elevates from an end of the syringe a distance proportional to the set dose." Ex. 1015 ¶ 1. Figure 1 of Moller is reproduced below.

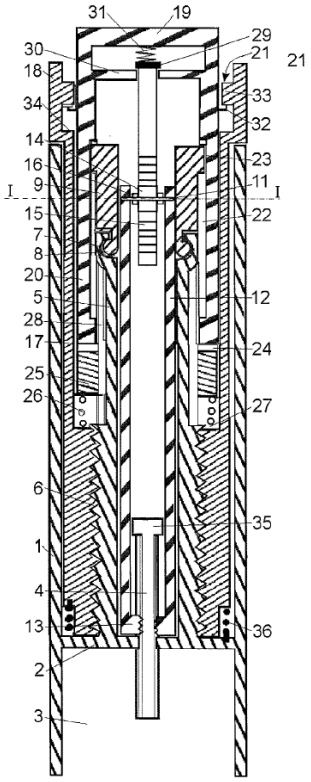

Fig. 1

Figure 1 shows a sectional view of an injection device. Ex. 1015 ¶ 17. The device includes housing 1 with partitioning wall 2 that divides housing 1 into two compartments, one with a dose setting mechanism and the other for accommodating an ampoule. *Id.* ¶ 22. Threaded piston rod 4 extends through an opening in wall 2 so that it can move longitudinally but not rotationally because threaded piston rod 4 has a non-circular cross section. *Id.* Tubular element 5 extends from the opening around threaded piston rod 4 and engages gearbox 9 so that gearbox 9 can rotate within housing 1. *See id.* ¶ 23.

Nut 13 engages the threads of the threaded piston rod 4 and connects to gearbox 9 via connection bars 12. *Id.* ¶ 24. Dose setting drum 17 engages thread 6 of tubular element 5 at one end and at the opposite end has an enlarged diameter forming dose setting button 18. *Id.* ¶ 25. Dose setting

drum 17 can be screwed into or out of housing 1 and includes a scale on its outer surface. Ex. 1015 ¶ 15.

A cup shaped element that fits over gearbox 9 and into dose setting drum 17 forms an injection button. *Id.* ¶ 26. The cup shaped element is coupled to dose setting drum 17 so that the cup shaped element, dose setting drum 17, and gearbox 9 rotate together. *Id.*

Dose setting button 18 is rotated to set a dose, which causes dose setting drum 17 to screw out with the cup shaped element. *Id.* ¶ 29. Bottom 19 of the cup shaped element is pressed to inject the set dose. *Id.* ¶ 32.

E. Ground Based on Steenfeldt-Jensen

1. Analysis of Claim 1

a) A housing part for a medication dispensing apparatus, said housing part comprising:

Petitioner argues that, if the preamble is limiting, Steenfeldt-Jensen teaches the preamble of claim 1. Pet. 22 (citing Ex. 1011 ¶¶ 261, 262; Ex. 1014, Abstract, 1:12–13, 5:38–44, Figs. 15–17).

To the extent that the preamble is limiting, we find that the relied-upon portions of Steenfeldt-Jensen teach "injection syringes of the kind apportioning set doses of a medicine from a cartridge" (Ex. 1014, 1:12–13) and the "injection syringe comprises a housing" (*id.* at Abstract). *See also id.* at 5:38–44 (describing that the "syringe comprise[s] a tubular housing 1"), Figs. 15–17. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 261, 262 (citing Ex. 1014, Abstract, 1:12–15, 5:38–44, Figs. 15–17).

Patent Owner does not present an argument regarding the preamble of claim 1. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-

Jensen teaches an injection syringe with a cartridge with medicine and a housing, Petitioner persuades us that Steenfeldt-Jensen teaches a "housing part for a medication dispensing apparatus."

b) a main housing, said main housing extending from a distal end to a proximal end;

Petitioner argues that, Steenfeldt-Jensen teaches the main housing of claim 1. Pet. 22–23 (citing Ex. 1011 ¶ 263; Ex. 1014, 5:38–44, Figs. 15–17, claim 11).

We find that the relied-upon portions of Steenfeldt-Jensen teach the syringe comprises housing 1 (Ex. 1014, 5:38–44) and has proximal and distal ends (*id.* at 14:9–40). *See also id.* at Figs. 15–17 (showing housing 1). We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 263 (citing Ex. 1014, 5:38–44, Figs. 15–17).

Patent Owner does not present an argument regarding the main housing of claim 1. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches an injection syringe with a housing having proximal and distal ends, Petitioner persuades us that Steenfeldt-Jensen teaches "a main housing, said main housing extending from a distal end to a proximal end."

c) a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;

Petitioner argues that Steenfeldt-Jensen teaches the dose dial sleeve of claim 1. Pet. 23–25 (citing Ex. 1011 ¶¶ 264, 265; Ex. 1014, 11:20–22, 11:52–54, 12:4–9, Figs. 15–17). Petitioner specifically argues that scale drum 80 is within housing 1 and includes the required helical track. Pet. 25 (citing Ex. 1011 ¶¶ 264, 265; Ex. 1014, 11:20–22, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib 16 along the inner wall of the housing 1," and "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing." Steenfeldt-Jensen also teaches:

> When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 which is induced by the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing.

Ex. 1014, 11:20–22, 11:52–54, 12:4–10. We also find that Figures 15 and 16 of Steenfeldt-Jensen show scale drum 80 within housing 1. We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 264, 265 (citing Ex. 1014, 11:20–22, 11:52–54, 12:4–9, Figs. 15–17).

Patent Owner does not present an argument regarding the dose dial sleeve of claim 1. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches that scale drum 80 is within housing 1 and has a helical track on its outer surface that engages helical rib 16 of housing 1, Petitioner persuades us that Steenfeldt-Jensen teaches "a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing."

d) a dose knob disposed near a proximal end of said dose dial sleeve;

Petitioner argues that Steenfeldt-Jensen teaches the dose knob of claim 1. Pet. 25–26 (citing Ex. 1011 ¶¶ 266, 267; Ex. 1014, 11:22–25,

11:52–62, Figs. 15–17). In particular, Petitioner argues that "Steenfeldt-Jensen explains scale drum 80 includes dose-setting button 81 at its button-end." *Id.* at 26 (citing Ex. 1014, 11:22–25, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[a]t its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81 which on its cylindrical outer wall is knurled to ensure a good finger grip," "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing," and "a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction." Ex. 1014, 11:22–25, 11:52–54, 11:57–58. We also find that Figures 15–17 of Steenfeldt-Jensen show dose setting button 81 at the button-end of scale drum 80. We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 266, 267 (citing Ex. 1014, 11:22–25, 11:52–62, Figs. 15–17).

Patent Owner does not present an argument regarding the dose knob of claim 1. *See* PO Resp. 30–54. Because Steenfeldt-Jensen teaches dose setting button 81 at the proximal end of scale drum 80, Petitioner persuades us that Steenfeldt-Jensen teaches "a dose knob disposed near a proximal end of said dose dial sleeve."

> *e) a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;*

Petitioner argues that Steenfeldt-Jensen the piston rod of claim 1. Pet. 26–29 (citing Ex. 1011 ¶¶ 268–271; Ex. 1014, 5:55–58, 11:6–19, 11:52–62, Figs. 15–17). Specifically, Petitioner argues that Steenfeldt-

Jensen teaches piston rod 6 and "a pawl mechanism that works between driver tube 85 and member 40" to "prevent[] the piston rod's rotation relative to housing 1 during dose setting by barring rotation of driver tube 85, to which piston rod 6 is rotationally fixed." *Id.* at 28 (citing Ex. 1011 ¶¶ 269–271; Ex. 1014, 5:55–58, 11:6–19, 11:52–62).

We find that the relied-upon portions of Steenfeldt-Jensen teach "piston rod 6 having an external thread 7 mating the thread 5 of said bore" and piston rod 6 "extends through said bore." Ex. 1014, 5:55–58. We also find that Figure 16 shows piston rod 6 in housing 1. We further find that the relied-upon portions of Steenfeldt-Jensen teach that "the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment," and "[t]he piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section" so that "rotation is transmitted" and "the piston rod is allowed to move longitudinally through the driver tube." *Id.* at 11:11–19.

Regarding piston rod 6 being non-rotatable relative to housing 1 during dose setting, we find that Steenfeldt-Jensen teaches a pawl mechanism between the driver tube that rotates piston rod 6 and housing 1 and that the pawl mechanism prevents the driver tube from rotating during dose setting. In particular, Steenfeldt-Jensen teaches that "[t]o maintain a clockwise rotation of a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing . . . bars clockwise rotation . . . of the driver tube." Ex. 1014, 11:6–11. Steenfeldt-Jensen also teaches that "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the

housing and the dose setting button is lifted away from the proximal end of the housing" and "[t]he bushing is kept non rotated due to its coupling to the driver tube which is locked against clockwise rotation." *Id.* at 11:52–57. "[I]f a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction," Steenfeldt-Jensen teaches that "the pawl mechanism working between the driver tube and the housing . . . prevent the bushing 82 from following this anticlockwise rotation." *Id.* at 11:57–62. We additionally credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 268–271 (citing Ex. 1014, 5:55–58, 8:35–42, 8:49–53, 11:6–19, 11:52–62, Figs. 15–17).

Patent Owner does not present an argument regarding the piston rod of claim 1. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches piston rod 6 in housing 1 and a pawl mechanism bars rotation of the driver tube that would rotate piston rod 6 during dose setting, Petitioner persuades us that Steenfeldt-Jensen teaches "a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing."

> *f) a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and,*

Petitioner argues that Steenfeldt-Jensen teaches the driver of claim 1. Pet. 29–30 (citing Ex. 1011 ¶¶ 273–276; Ex. 1014, 11:6–19, 12:4–12, Figs. 16, 17). Petitioner also argues that it would have been obvious to modify driver tube 85 to provide the driver of claim 1. *Id.* at 30 (citing Ex. 1011 ¶¶ 275–279).

We find that Figure 16 of Steenfeldt-Jensen shows driver tube 85 around a portion of piston rod 6. Also, as discussed above for the recited

piston rod, Steenfeldt-Jensen teaches that "the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment," and "[t]he piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section" so that "rotation is transmitted" and "the piston rod is allowed to move longitudinally through the driver tube." Ex. 1014, 11:11–19.

We also find that the relied-upon portions of Steenfeldt-Jensen teach that pressing injection button 88 injects a set dose, "the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing" induces "anticlockwise rotation of the dose setting button 81," bushing 82 follows that rotation, "[t]he bushing will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows," and "the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.* at 12:4–12; *see also id.* at 11:6–11 (describing the pawl mechanism), 11:52–62 (describing dose setting).

Patent Owner responds that "Petitioner concedes that Steenfeldt-Jensen's fifth embodiment does not disclose this limitation." PO Resp. 30 (citing Pet. 30). Patent Owner also responds that "[n]one of the four passages in Steenfeldt-Jensen that Petitioner relies on discloses an internally threaded driver tube," and that "these passages only disclose an internally threaded 'nut member' or 'nut element', which is rotated by a driver tube – the driver tube itself is not threaded—Steenfeldt-Jensen's driver tube itself is never threaded." *Id.*; *see also id.* at 30–32 (arguing what the passages would

teach to one of ordinary skill in the art) (citing Ex. 1014, 2:40–53, 3:15–20, 3:41–47, 7:44–47, 10:2–10, Fig. 13; Ex. 2107 ¶¶ 215–217).

We agree with Patent Owner that Petitioner argues that Steenfeldt-Jensen teaches that "[t]o drive piston rod 6, driver tube 85 rotationally engages with the rod through the non-circular bore, rather than 'an internal threading near a distal portion.'" Pet. 30 (citing Ex. 1011 ¶ 274). Petitioner, however, further argues that one of ordinary skill in the art "would have considered it obvious to modify driver tube 85 to provide the 'driver' of claim 1," which we analyze below. *Id.* (citing Ex. 1011 ¶¶ 275–279).

For the reasons above, because Steenfeldt-Jensen teaches driver tube 85 around a portion of piston rod 6, Petitioner persuades us that Steenfeldt-Jensen teaches "a driver extending along a portion of said piston rod" that rotates the piston rod via a non-circular bore so that piston rod screws through internal threading of end wall 4.

(1) Reason to Modify

Regarding "said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod," Petitioner argues that, although Steenfeldt-Jensen teaches driver tube 85 engaging piston rod 6 via a non-circular bore, one of ordinary skill in the art would have "modif[ied] the device to provide driver tube 85 with an internal threading near its distal portion" so that the "modified device would have been understood to contain a 'driver' having the claimed structural elements." Pet. 35 (citing Ex. 1011 ¶ 274).

(a) Steenfeldt-Jensen Would Have Suggested a Driver with Internal Threading to One of Ordinary Skill in the Art

According to Petitioner, Steenfeldt-Jensen contemplates the proposed modification because it states that "[e]mbodiments may be imagined

wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube." *Id.* (quoting Ex. 1014, 7:44–47) (citing also Ex. 1011 ¶ 275; Ex. 1014, 3:15–20, 3:44–47) (alteration in original). Also, according to Petitioner, "Steenfeldt-Jensen explains the piston rod guide is a structure that allows the piston rod to move axially relative to it, but not rotatably, whereas the nut element is a structure that allows for relative rotation." *Id.* at 36 (citing Ex. 1011 ¶ 276; Ex. 1014, 2:46–53, 3:15–20).

Petitioner contends that, based on Figures 15–17 of Steenfeldt-Jensen, one of ordinary skill in the art "would have understood that driver tube 85 includes a 'piston rod guide' because its bore allows relative axial movement of the piston rod, but prevents relative rotation" and that "member 40 includes a 'nut element' due to its internal threading in wall 4." *Id.* (citing Ex. 1011 ¶ 276). Petitioner also contends that, because of a suggestion to provide the "nut element" on the driver tube, one of ordinary skill in the art would have modified "(1) driver tube 85 to include an internal threading for engaging the piston rod's external threading and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod," thereby meeting all the limitations of claim 1. Pet. 36 (citing Ex. 1011 ¶ 277). Petitioner further contends that one of ordinary skill in the art would have expected the modified device to operate in the same manner as before and thus would perform the same function it was known to perform. *Id.* at 36–37 (citing Ex. 1011 ¶ 278).

Patent Owner responds that (1) Steenfeldt-Jensen refers only to a "nut member" or "nut element" with internal threads, not a driver tube; (2) even if Steenfeldt-Jensen can be said to suggest modifying its driver tube, the suggestion applies only to Steenfeldt-Jensen's first embodiment, not its fifth embodiment; and (3) one of ordinary skill in the art would not have been

motivated to apply Petitioner's modification to the fifth embodiment because the modification would result in an inferior device with significantly higher injection force. PO Resp. 1.

Patent Owner argues that one of ordinary skill in the art would have understood that column 7, lines 44–47 of Steenfeldt-Jensen relates only to the first embodiment of Steenfeldt-Jensen, not the fifth embodiment shown in Figures 15–17 that Petitioner proposes modifying. *Id.* at 32–33 (citing Ex. 1014, 7:41–47; Ex. 2107 ¶¶ 223–226). Patent Owner also argues that the phrase "shown embodiment" in that part of Steenfeldt-Jensen refers to the first embodiment shown in Figures 1–5, the description of the fifth embodiment does not include a statement similar to "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube," and the provisional application included the statements at lines 41–47 of column 7, describing the first embodiment, but no similar description for the fifth embodiment. PO Resp. 33 (citing Ex. 1014, 5:33–7:47, 11:6–12:16; Ex. 2127, 11:2–5).

Patent Owner additionally argues that one of ordinary skill in the art would not have understood that lines 41–47 of column 7 is applicable to all embodiments of Steenfeldt-Jensen because, for example, applying it to Steenfeldt-Jensen's second embodiment results in a non-functioning pen injector. *Id.* at 33–34 (citing Ex. 2107 ¶ 226). Patent Owner further argues that, even if applied to the fifth embodiment, lines 41–47 of column 7 does not teach or suggest Petitioner's proposed modification. *Id.* at 34 (citing Pet. 36; Ex. 2107 ¶ 227; Ex. 2164, 219:18–220:11). According to Patent Owner, "it teaches putting a piston rod guide in end wall 4 of ampoule holder 2 (of the first embodiment), and having driver tube 26 (of the first embodiment) rotate a nut element." *Id.* (citing Ex. 2107 ¶ 215).

Petitioner replies that "a driver with a nut member *is* an internally-threaded driver" and that one of ordinary skill in the art would have understood "Steenfeldt-Jensen describes an internally-threaded driver tube when referring to a driver rotating a nut member." Pet. Reply 3 (citing PO Resp. 30; Ex. 1095 ¶¶ 63–64; Ex. 2107 ¶¶ 215–222). Petitioner contends that one of ordinary skill in the art would have understood Steenfeldt-Jensen teaches "an internally-threaded driver tube when referring to a driver rotating a nut member," because Steenfeldt-Jensen describes the well-known alternative of a driver rotating a nut member or nut element, and that, because no meaningful distinction exists between an integral piston-rod guide and rectangular bore, no meaningful distinction exists between an integral nut member and threads. Pet. Reply 4 (citing Pet. 35; Ex. 1014, 3:41–47, 6:35–36, 11:15–19; Ex. 1095 ¶ 65; Ex. 2107 ¶ 30).

Petitioner also replies that one of ordinary skill in the art would have been able to apply relevant teachings from one embodiment to another. *Id.* at 5 (responding to PO Resp. 29–32). Petitioner argues that Steenfeldt-Jensen teaches alternative driver mechanisms before describing other embodiments and Patent Owner ignores the broader context. *Id.* (citing Pet. 36; PO Resp. 25; Ex. 1014, 2:46–53, 3:15–20; Ex. 1095 ¶ 66). Because Steenfeldt-Jensen teaches alternative driver mechanisms before describing other embodiments, Petitioner contends that one of ordinary skill in the art would have known such alternatives would also apply to the fifth embodiment and such a general suggestion does not have to be repeated. *Id.* at 5–6 (citing Ex. 1014, 2:40–53, 3:10–20, 3:41–47; Ex. 1095 ¶¶ 66–69).

Petitioner further replies that the first and fifth embodiments have analogous features so that one of ordinary skill in the art would have understood that the alternative configuration for the first embodiment applies

to the fifth embodiment and the alternative would have been the same with the same effect. *Id.* at 6–7 (citing Ex. 1095 ¶¶ 68–69). Petitioner further contends that whether the alternative configuration could be applied to the second embodiment is irrelevant because of the second embodiment's different drive mechanism and Patent Owner's declarant agreed that the second embodiment's drive mechanism is different. *Id.* at 7–9 (citing Ex. 1014, 7:51–54, Figs. 6–10; Ex. 1054, 306:23–308:9, 342:3–343:18, 344:7–346:25; Ex. 1095 ¶ 70).

Patent Owner replies that "Steenfeldt-Jensen nowhere discloses a threaded driver tube," and thus, "the parties' arguments about whether the 7:41–47 applies to the fifth embodiment are moot." PO Sur-reply 1 (citing PO Resp. 30–32). Patent Owner also replies that it addressed other parts of Steenfeldt-Jensen that Petitioner cites. *Id.* (citing PO Resp. 30–32; Pet. Reply 5). Patent Owner argues that Petitioner concedes that lines 41–47 of column 7 "is not a blanket statement," Petitioner's declarant acknowledges but dismisses differences between embodiments, and Petitioner turns to analogous structures and avoiding redundancy to apply lines 41–47 of column 7 to the fifth embodiment. *Id.* at 1–2 (citing Pet. Reply 6, 7; Ex. 1095 ¶ 68).

Patent Owner also argues that the "embodiments are not analogous" and one of ordinary skill in the art "would not take a teaching specific to the first embodiment and apply it to the fifth embodiment." *Id.* at 2 (citing PO Resp. 23–26). Patent Owner further contends that Dr. Slocum opined about Petitioner's modification. *Id.* at 2–3 (citing Pet. Reply 9–10). Patent Owner argues that the increased injection force indicates that one of ordinary skill in the art would not be motivated to make Petitioner's modification. *Id.* at 4 (citing Pet. Reply 11).

Patent Owner also replies that "the claims specifically require a threaded driver tube," Steenfeldt-Jensen's nut member is separate from the driver tube, and Petitioner misreads lines 41–47 of column 3. *Id.* at 7–8 (citing Pet. Reply 3, 4). Patent Owner contends that the first, third, fourth, and fifth embodiments have a nut member distinct from a driver tube and lines 41–47 of column 3 does not mention an integrally formed nut member. *Id.* at 8–10 (citing Ex. 1014, 3:41–47, Figs. 2, 12, 14, 16).

Patent Owner also contends that Petitioner incorrectly asserts that a driver tube with integral piston rod guide suggests a driver tube with integral nut member because Steenfeldt-Jensen does not equate the piston rod guide and the nut member. PO Sur-reply 10–11 (citing Pet. Reply 3–4; Ex. 1014, 3:41–47). According to Patent Owner, lines 41–47 of column 3 "at best, draws a parallel between a piston rod (not a piston rod guide) and nut member, but does not suggest an integrally formed nut member." Patent Owner further contends that another relied-upon portion of Steenfeldt-Jensen does not suggest a nut member integrally formed with a driver tube. *Id.* at 11 (citing Pet. Reply 4; Ex. 1014, 7:41–43).

We agree with Patent Owner that the phrase "[i]n the shown embodiment" refers to Steenfeldt-Jensen's first embodiment because (1) the language comes at the end of the written description of the first embodiment and refers to *the shown* embodiment (i.e., the embodiment that was shown previously in the written description of Steenfeldt-Jensen, meaning in Figures 1–5), (2) the only embodiment previously *shown* is that of the first embodiment, and (3) the references to end wall 4, piston rod guide 14, and driver tube 26 are described and shown as components of the first

embodiment. Ex. 1014, 7:41–43.[6] We also find that the language that follows expressly teaches other embodiments "wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube." *Id.* at 7:44–46. Because this teaching comes after describing the first embodiment, we determine that this express teaching applies to the first embodiment.

We also find that Steenfeldt-Jensen discloses the disputed alternative in the express context of the first embodiment. As argued by Petitioner, we further find that one of ordinary skill in the art would have, at a minimum, considered whether the alternative described therein also would apply to other embodiments, even though the alternative is not repeated after the discussion of each embodiment. We agree with Petitioner that this express teaching would have, at least, suggested to one of ordinary skill in the art to consider applying a similar alternative to other embodiments as well, particularly the fifth embodiment and would have applied the teaching to the other embodiments. *See* Pet. 35–36; Pet. Reply 5–7. We credit Mr. Leinsing's testimony regarding Steenfeldt-Jensen's suggestion because, for the reasons discussed below, the full record before us supports it. Ex. 1011 ¶ 277.

We agree with Petitioner and find that the various embodiments of Steenfeldt-Jensen have either analogous or the same components. *See* Pet. Reply 5–6. For example, the first embodiment includes "wall 4 having a central bore with an internal thread 5" and "piston rod 6 having an external thread 7 mating the thread 5 of said bore" (Ex. 1014, 5:56–58); the second

[6] Steenfeldt-Jensen does not use reference numbers for the end wall, piston rod guide, and driver tube of the fifth embodiment. *See* Ex. 1014, 11:11–19.

embodiment has a piston rod (*id.* at 7:64); the third embodiment includes "piston rod 6 [that] engages by its external thread 7 the internal thread of the end wall 4" (*id.* at 8:45–46); the fourth embodiment also has an internally threaded wall 4 that is not described but shown in Figure 14; and for the fifth embodiment, "the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall" (*id.* at 11:11–14). *See also id.* at Fig. 2 (showing, for the first embodiment, externally threaded piston rod 6 engaging internally threaded wall 4), Fig. 7 (showing, for the second embodiment, externally threaded piston rod 6 engaging internally threaded wall 4), Figs. 11–12 (showing, for the third embodiment, externally threaded piston rod 6 engaging internally threaded wall 4), Fig. 14 (showing, for the fourth embodiment, internally threaded wall 4), Figs. 15–16 (showing, for the fifth embodiment, externally threaded piston rod 6 engaging internally threaded wall 4).

Based on the portions of Steenfeldt-Jensed discussed above, we find that one of ordinary skill in the art would applied lines 44–47 of column 7 to embodiments with the same or analogous components—the first, third, fourth, and fifth embodiments—because lines 44–47 of column 7 relate to, at least, end wall 4, which is included in each of those embodiments. Ex. 1011 ¶ 277; Ex. 1095 ¶ 69. We also find that the first and fifth embodiments have substantially similar arrangements of piston rods, piston rod guides, and nut members. *Compare id.* at Fig. 3 *with id.* at Fig. 17; *see also* Ex. 1054, 306:23–308:9 (Dr. Slocum testifying that driver tubes and piston rods shown in Figs. 3 and 17 work similarly), 342:3–343:18 (Dr. Slocum testifying that driver tubes of the first and fifth embodiments work similarly).

We recognize, as Patent Owner points out, that one of ordinary skill in the art may not have applied the taught or suggested alternative arrangement to the second embodiment because of differences in the structure of the second embodiment as compared to the first. *See* PO Resp. 33–34. That the alternative arrangement may not have applied to the second embodiment, however, does not lead to the conclusion that one of ordinary skill in the art would not have or could not have applied the taught or suggested alternative to Steenfeldt-Jensen's other embodiments. *See* Ex. 1095 ¶ 70.

Regarding whether Steenfeldt-Jensen would have taught or suggested a driver tube with an integral nut element, Petitioner provides evidence that one of ordinary skill would have understood lines 41–47 of column 3 to suggest such a driver tube. *See* Pet. Reply 3–4 (citing Pet. 35; Ex. 1014, 3:41–47, 6:35–36, 11:15–19; Ex. 1095 ¶ 65; Ex. 2107 ¶ 30). Patent Owner provides a refuting argument with support from what Steenfeldt-Jensen expressly describes, but that does not address directly Petitioner's contention that one of ordinary skill in art would have understood that Steenfeldt-Jensen *suggests* a driver tube with integral nut member. *See* PO Sur-reply 10–11 (citing Pet. Reply 3–4; Ex. 1014, 3:41–47, 7:41–43).

We find that Petitioner establishes Steenfeldt-Jensen would have suggested a driver tube with an integral nut element to one of ordinary skill in the art at the time of the invention. In particular, Petitioner sufficiently shows that, even if Steenfeldt-Jensen does not teach expressly a driver tube with an integral nut element, Steenfeldt-Jensen, at lines 41–47 of column 3, suggests such a driver tube, and the understanding of one of ordinary skill in the art would not have been limited to only the express teachings. *See* Pet. 35–37; Pet. Reply 3–4; Ex. 1011 ¶ 277; Ex. 1014, 3:41–47, 6:35–36, 11:15–19; Ex. 1095 ¶¶ 63–65, 69; Ex. 2107 ¶ 30. Based on the full record,

we find persuasive, and thus credit, Mr. Leinsing's testimony that "a driver tube with a nut member is equivalent to a driver tube with an internally-threaded bore." Ex. 1095 ¶ 65. Patent Owner's argument—that an internally threaded driver tube is not disclosed expressly—does not detract from Petitioner's contention and Mr. Leinsing's testimony that one of ordinary skill in art would have understood that Steenfeldt-Jensen *suggests* a driver tube with an internally-threaded bore. *See* PO Sur-reply 10–11 (citing Pet. Reply 3–4, 17–18; Ex. 1014, 3:41–47, 7:41–43).

On the full record before us, we find that Petitioner sufficiently shows that, even though Steenfeldt-Jensen does not *disclose* a driver with internal threading, one of ordinary skill in the art would have understood Steenfeldt-Jensen, at lines 41–47 of column 3, to *suggest* such a driver. *See* Pet. 35–37; Pet. Reply 3–4; Ex. 1011 ¶ 277; Ex. 1095 ¶ 69.

(b) One of Ordinary Skill in the Art Would Have Modified Steenfeldt-Jensen's Fifth Embodiment

Petitioner contends that, based on Figures 15–17 of Steenfeldt-Jensen, one of ordinary skill in the art "would have understood that driver tube 85 includes a 'piston rod guide' because its bore allows relative axial movement of the piston rod, but prevents relative rotation" and that "member 40 includes a 'nut element' due to its internal threading in wall 4." Pet. 36 (citing Ex. 1011 ¶ 276). Petitioner also contends that, because of a suggestion to provide the "nut element" on the driver tube, one of ordinary skill in the art would have modified "(1) driver tube 85 to include an internal threading for engaging the piston rod's external threading and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod," thereby meeting all the limitations of claim 1. *Id.* (citing Ex. 1011 ¶ 277). Petitioner further contends that one of ordinary skill in the

art would have expected the modified device to operate in the same manner as before and thus would perform the same function they were known to perform. *Id.* at 36–37 (citing Ex. 1011 ¶ 278).

For the reasons above, Petitioner persuades us that one of ordinary skill in the art, reading that other embodiments can have a "piston rod guide [that] is provided in the wall 4 and a nut element [that] is rotated by the driver tube" (Ex. 1014, 7:44–46), "would have reason to modify (1) driver tube 85 to include an internal threading for engaging the piston rod's external threading, and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod" in Steenfeldt-Jensen's fifth embodiment. Pet. 36. We also agree with Petitioner that one of ordinary skill in the art would have reasonably expected the modified parts to perform the same function as before, and thus, one of ordinary skill in the art would have had a reasonable expectation of success in making Petitioner's proposed modification. *See* Pet. 36–37 (citing Ex. 1011 ¶ 278). We further credit Petitioner's declarant testimony regarding Petitioner's proposed modification because it finds support in Steenfeldt-Jensen. Ex. 1011 ¶¶ 275–278 (citing Ex. 1014, 2:46–53, 3:15–20, 3:44–47, 7:44–47, 8:48–53, Figs. 15–17).

For the reasons above, we determine that Petitioner's modified driver tube 85 rotating a nut member with internal threading engaging externally threaded piston rod 6 would result in "said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod," as required by claim 1.

(c) One of Ordinary Skill in the Art Would Not Have Been Dissuaded from Modifying Steenfeldt-Jensen Because It Would Have Resulted in an Inferior Pen

Patent Owner also responds that Petitioner's proposed modification to switch the non-circular opening and threaded opening of Steenfeldt-Jensen's fifth embodiment would result in an inferior pen and thus, one of ordinary skill in the art would not have been motivated to make Petitioner's proposed modification. PO Resp. 35–45; *see also id.* at 1 (arguing that Petitioner's proposed modification "would result in an inferior device with significantly higher injection force"). In particular, Patent Owner argues that moving threads to the driver tube and moving the non-circular bore to member 40 would cause "***a major new source of friction*** to Steenfeldt-Jensen's fifth embodiment" and thus, one of ordinary skill in the art would not have been motivated to make Petitioner's modification. PO Resp. 35 (citing Ex. 2107 ¶¶ 212–255).

Patent Owner contends that higher friction would increase injection force, which is a benchmark. *Id.* (citing Ex. 1015 ¶¶ 4–6; Ex. 2107 ¶¶ 37–39, 44–45, 54, 56–57; Ex. 2163, 80:17–81:5). For support of its argument, Patent Owner points us to "an analytical model" and "a physical model (the 'Collar Friction Model')." PO Resp. 36 (citing Ex. 2107 ¶¶ 245–255); *see also id.* at 36–37 (explaining the analytical model and contending that it shows "Petitioner's proposed modification increases the amount of force required from the user to inject a dose by 51%") (citing Ex. 2107, App'x A ¶¶ 242–244), 37–41 (explaining the Collar Friction Model and contending that "manually rotating the Collar with the Threaded Insert requires 50% more force on average to advance the piston rod than rotating the Collar with Guide") (citing Ex. 2107 ¶¶ 245–255; Ex. 2215; Ex. 2216; Ex. 2217 (video

demonstratives explaining friction in Steenfeldt-Jensen and modifications)), 41–45 (explaining why Petitioner's modification results in higher friction) (citing Ex. 1004, 1:36–40 (Veasey '844 patent on pen injector needs)); Ex. 1014, 12:10–13, Fig. 16; Ex. 1015 ¶¶ 4–6; Ex. 2107 ¶¶ 54–57, 229–231, 233–238, 242–244; Ex. 2152 (animation showing different places of force injection)).

Petitioner replies that Patent Owner's models are based on Dr. Slocum ignoring Steenfeldt-Jensen's suggested alternative for the fifth embodiment but that Dr. Slocum agreed that the suggestion expressly applied to the first embodiment. Pet. Reply 9–10 (citing PO Resp. 26–39; Ex. 1054, 306:23–308:9, 308:15–313:6). Petitioner also argues that Patent Owner assumes incorrectly that one of ordinary skill in the art would focus on designing only insulin pens. *Id.* at 10–11 (citing PO Resp. 27–28; Ex. 1053, 62:13–71:2, 72:3–11, 75:22–76:3; Ex. 2107 ¶¶ 44–61). According to Petitioner, the claim and asserted references are not limited to such pens. *Id.* at 10. Petitioner agrees that injection force is a factor, but argues that it is not the only factor one of ordinary skill in the art would have considered when designing pen injectors. *Id.* at 11 (citing Ex. 1048 ¶¶ 26, 28, 32; Ex. 1095 ¶ 72). Petitioner notes that Patent Owner "never alleges the modification is inoperable or a [person of ordinary skill in the art] would not have reasonably expected success" because "the modification is straightforward so its workability cannot be questioned." Pet. Reply 11 (citing Ex. 1095 ¶ 72).

Petitioner also replies that Patent Owner's models are flawed because (1) a named inventor provided most of the inputs for the analytical model spreadsheet (*id.* at 12–14 (citing PO Resp. 28–29; Ex. 1053, 12:22–13:5, 28:18–29:2, 30:5–33:13; Ex. 1054, 313:10–325:12; Ex. 1095 ¶¶ 73, 74;

Ex. 2107 ¶¶ 242–243)), (2) the models focus on friction at one point and ignores reductions in friction (*id.* at 14–15 (citing Ex. 1095 ¶ 75; Ex. 2107 ¶ 58)), and (3) the models exaggerate friction losses by not considering ordinary creativity in minimizing friction (*id.* at 15–16 (citing Ex. 1053, 33:5–13, 41:3–42:13; Ex. 1054, 325:22–327:6; Ex. 1095 ¶¶ 73–75)).

Patent Owner replies that Patent Owner's declarant shows that Petitioner's proposed modification would result in higher injection force and that Petitioner "identif[ies] no other application where a higher injection force would be acceptable." PO Sur-reply 3 (citing PO Resp. 32–47; Pet. Reply 10); *see also id.* at 4 (arguing that "injection force would increase—a fact not disputed (only the amount)"). Patent Owner argues that Patent Owner's declarant "verified the models, conducted his own experiments, and gathered his own data" and the named inventor is not an employee and has no financial stake in the outcome of this proceeding. *Id.* at 5 (citing Pet. Reply 12–14; Ex. 2107 ¶¶ 242–255). Patent Owner also argues that the "51% increase in injection force is derived from a comparison of the fifth embodiment and the modified fifth embodiment." *Id.* at 6 (citing Pet. Reply 14–58). Patent Owner further argues that any friction mitigation applied to the modified fifth embodiment would also be "equally applied to the unmodified fifth embodiment and thus would be a wash." *Id.* at 7 (citing Pet. Reply 15). Patent Owner lastly replies that Petitioner did not inspect Patent Owner's models and presents no refuting evidence. *Id.* at 5, 6, 7 (citing Ex. 2316, 17:17–18:24).

We find that the first and fifth embodiments have substantially similar arrangements of piston rods, piston rod guides, and nut members. *Compare* Ex. 1014, Fig. 3, *with id.* at Fig. 17. Patent Owner presents persuasive evidence that Petitioner's proposed modification would increase friction to

some extent. Nonetheless, Steenfeldt-Jensen expressly teaches an alternative configuration wherein a piston rod guide is in wall 4 and a driver tube rotates a nut element instead of a piston rod guide. *See id.* at 7:41–47. Petitioner provides persuasive evidence that at least some of the friction increase could be offset by making routine changes well within the level of ordinary skill in the art and that the increase would not have dissuaded one of ordinary skill in the art from applying the alternative disclosed in Steenfeldt-Jensen to the fifth embodiment. Ex. 1095 ¶¶ 73–75.

Additionally, even if we assume, as Patent Owner contends, that Steenfeldt-Jensen's alternative arrangement were limited to the first embodiment, Patent Owner's models indicate that, by implementing that alternative in the first embodiment, friction would also increase. Despite this result, Steenfeldt-Jensen does not indicate that the alternative configuration for the first embodiment has higher friction or that any resulting increase in friction is a cause for concern. *See* Ex. 1014, 7:41–47. Therefore, Steenfeld-Jensen's disclosure further supports our finding that an increase in friction would not have dissuaded one of ordinary skill in the art from making Petitioner's proposed modification to Steenfeldt-Jensen's fifth embodiment.

(d) One of Ordinary Skill in the Art Would Not Have Been Dissuaded from Modifying Steenfeldt-Jensen Because of Potential Failures in the Flexible Arms of the Driver Tube

Patent Owner also contends that there are other potential failures in Petitioner's proposed modification. PO Resp. 45–46. Specifically, Patent Owner argues that flexible arms of driver tube 85 that act as a ratchet with member 40 can break, get stuck, or become jammed in an opening in a ring-

shaped wall. *Id.* (citing Ex. 1014, 11:55–62, Figs. 15, 16; Ex. 2107 ¶¶ 239–241).

Petitioner replies that Patent Owner offers no evidence that the flexible arms would be affected and that one of ordinary skill in the art could address the asserted potential failures as a "routine task without difficulty." Pet. Reply 16 (citing PO Resp. 45–46; Ex. 1095 ¶ 76; Ex. 2107 ¶¶ 239–241). Patent Owner replies that Petitioner presents no evidence that addressing these potential failures would be routine. PO Sur-reply 4–5 (citing Pet. Reply 16).

As discussed above, Steenfeldt-Jensen expressly describes an alternative configuration wherein a piston rod guide is in wall 4 and a driver tube rotates a nut element instead of a piston rod guide. *See* Ex. 1014, 7:41–47. Steenfeldt-Jensen does not address whether the alternative configuration results in potential failures in the flexible arms of the alternative driver tube. *See id.* Dr. Slocum opines that there may be potential issues with these flexible arms in Petitioner's proposed modification, but that testimony does not cite sufficient supporting evidence. *See* Ex. 2107 ¶¶ 239–241. Thus, because Steenfeldt-Jensen proposes a similar modification and does not address potential failures in the flexible arms of the alternative driver tube, and because Dr. Slocum, as one of ordinary skill in the art, recognizes these potential failures, the full record persuades us that such potential failures are matters that would have been recognized by ordinarily skilled artisans and would have been addressed by those artisans. Therefore, based on the full record before us, Patent Owner's asserted potential failures in the flexible arms of the alternative driver tube do not show that one of ordinary skill in the art would have been dissuaded from making Petitioner's proposed modification.

(e) Determination as to the Reason to Modify

For the reasons above, based on the full record before us, Petitioner persuades us that Steenfeldt-Jensen suggests Petitioner's proposed modifications. Petitioner persuades us that the expressly taught modification for Steenfeldt-Jensen's first embodiment would have suggested to one of ordinary skill in the art to modify Steenfeldt-Jensen's fifth embodiment.

Petitioner also presents arguments based on Exhibit 1016.[7] Pet. Reply 16–18 (citing Ex. 1016, 3:1–26, Figs. 2, 3, 5–7; Ex. 1054, 308:10–310:22; Ex. 1095 ¶ 77). Patent Owner argues that Petitioner presents a new argument based on Exhibit 1016. PO Sur-reply 11–12 (citing Pet. Reply 16–18). We do not need to address Exhibit 1016 because, for the reasons above, Petitioner persuades us that one of ordinary skill in the art would have made Petitioner's proposed modification based on arguments made in the Petition.

g) a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob,

Petitioner argues that Steenfeldt-Jensen teaches the tubular clutch of claim 1. Pet. 30–33 (citing Ex. 1011 ¶¶ 280–283; Ex. 1014, 11:26–42, 11:52–62, 12:1–13, Figs. 15–17). Specifically, Petitioner argues that bushing 82 teaches the tubular clutch because rosette 93 of teeth engaged teeth on dose setting button 81 during injection and disengage during dose setting. *Id.* at 32–33 (citing Ex. 1011 ¶¶ 280–283; Ex. 1014, 11:26–42, 11:52–62, 12:1–13, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "bushing 82 ha[s] a flange 83 at its proximal end" (Ex. 1014, 11:26), "[i]n the dose setting button a compartment is . . . provided with . . . a bottom with

[7] Giambattista, U.S. Patent No. 6,932,794 B2, issued August 23, 2005.

a rosette of teeth having a triangular cross-section" (*id.* at 11:34–37), "flange 83 of the bushing 82 is adopted in said compartment" (*id.* at 11:37–38), and "[a]t its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment" (Ex. 1014, 11:40–42).

We also find that the relied-upon portions of Steenfeldt-Jensen teach that "[d]uring the setting the rosette in the dose setting button forces the rosette 93 on the flange 83 of the bushing 82 out of engagement" (*id.* at 12:1–3) and "[w]hen the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81" (*id.* at 12:4–7). As discussed above for the recited "dose knob," Petitioner argues that dose setting button 81 of Steenfeldt-Jensen teaches the "dose knob." Pet. 25–26 (citing Ex. 1011 ¶¶ 266, 267; Ex. 1014, 11:22–25, 11:52–62, Figs. 15–17). We additionally find that Figures 15–17 show bushing 82 is tubular and located near dose setting button 81. We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 280–283 (citing Ex. 1014, 11:26–49, 11:52–62, 12:1–13, Figs. 15–17).

Patent Owner does not present an argument regarding the tubular clutch of claim 1. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches bushing 82 is tubular, located near dose setting button 81, and can engage or disengage with dose setting button 81, Petitioner persuades us that Steenfeldt-Jensen teaches "a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob."

h) wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Petitioner argues that Steenfeldt-Jensen teaches the wherein clause of claim 1. Pet. 33–34 (citing Ex. 1011 ¶¶ 285; Ex. 1014, 11:26–28, Figs. 15, 16). As discussed above, Petitioner contends that Steenfeldt-Jensen's scale drum 80 teaches the dose dial sleeve. Pet. 25 (citing Ex. 1011 ¶ 264; Ex. 1014, 11:20–22, Figs. 15–17).

We find that the relied-upon portion of Steenfeldt-Jensen teaches that "bushing 82 . . . fits into the scale drum 80." Ex. 1014, 11:26–28. We also find that Figures 15 and 16 of Steenfeldt-Jensen show scale drum 80 circumferentially around a portion of bushing 82. We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 285 (citing Ex. 1014, 11:28–30, Figs. 15–16).

Patent Owner does not present an argument regarding the final wherein clause of claim 1. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches scale drum 80 circumferentially around a portion of bushing 82, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch."

2. Analysis of Claim 2

Claim 2 depends from claim 1 and recites "wherein said tubular clutch is directly coupled to said dose knob." Ex. 1003, 7:13–14.

Petitioner refers to its arguments for the tubular clutch of claim 1. Pet. 37. Petitioner also argues that "bushing 82 is directly coupled to dose-setting button 81" and "teeth 93 of bushing 82 releasably engage teeth in the dose-setting button during injection to couple the components." *Id.* (citing Ex. 1011 ¶ 290; Ex. 1014, 11:34–51, Figs. 16, 17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[i]n the dose setting button a compartment is . . . provided with . . . a bottom with a rosette of teeth having a triangular cross-section" (Ex. 1014, 11:34–37), "flange 83 of the bushing 82 is adopted in said compartment" (*id.* at 11:37–38), and "[a]t its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment" (*id.* at 11:40–42). As discussed above for the tubular clutch of claim 1, Steenfeldt-Jensen teaches that, when pressing injection button 88 to inject a set dose, the rosettes of bushing 82 and dose setting button 81 are pressed into contact with each other so that both rotate at the same time. *See id.* at 12:4–7. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 290 (citing Ex. 1014, 11:34–40, 12:1–13, Figs. 15–17).

Patent Owner does not present an argument regarding claim 2. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches bushing 82 engaging with dose setting button 81, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said tubular clutch is directly coupled to said dose knob."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 2 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 2, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 2.

3. Analysis of Claim 3

Claim 3 depends from claim 1 and recites "wherein said main housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable." Ex. 1003, 7:15–17.

Petitioner argues that "[h]ousing 1 includes a window 18 through which numbers on the scale drum's outer surface is viewable." Pet. 37–38 (citing Ex. 1011 ¶¶ 291–293; Ex. 1014, 6:18–21, 7:31–33, Fig. 17).

We find that the a relied-upon portion of Steenfeldt-Jensen teaches that "[n]umbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1." Ex. 1014, 6:18–21; *see also id.* at 7:11–13 (stating that "[t]he size of the set dose can currently be seen on the part of the dose scale drum which is presented in the window 18"). We also find that Figure 17 shows window 18 of housing 1.

As discussed above, Petitioner argues that scale drum 80 of Steenfeldt-Jensen teaches the dose dial sleeve of claim 1. Pet. 23–25 (citing Ex. 1011 ¶¶ 264, 265; Ex. 1014, 11:20–22, 11:52–54, 12:4–9, Figs. 15–17). We credit Mr. Leinsing's testimony that, "[t]hus, a person of ordinary skill would have understood that 'a portion of an outer surface' of the scale drum 80 'may be viewable' through the window 18 of the housing 1," because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 291 (citing Ex. 1014, 6:18–21, 7:11–13, Fig. 17).

Patent Owner does not present an argument regarding claim 3. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches housing 1 includes window 18 through a portion of a scale drum can be viewed, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said

main housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 3 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 3, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 3.

4. Analysis of Claim 4

Claim 4 depends from claim 3 and recites "wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing." Ex. 1003, 7:18–20.

Petitioner argues that "FIG. 17 shows that window 18 is located near the button-end of housing 1" and that "[h]ousing 1 includes helical rib 16 on its inner surface, which is shown to run along its length, including near window 18." Pet. 37–38 (citing Ex. 1011 ¶¶ 293–294; Ex. 1014, 6:18–21, 11:20–22, Figs. 15–17).

As discussed above for claim 3, we find that Steenfeldt-Jensen teaches that housing 1 includes window 18. We also find that a relied-upon portion of Steenfeldt-Jensen teaches that "scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib 16 along the inner wall of the housing 1." Ex. 1014, 11:20–22. We further find that Figure 17 of Steenfeldt-Jensen shows that window 18 is near the button-end of housing 1 and that housing 1 includes helical rib 16 on an inner surface of housing 1. We additionally credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 293–294 (citing Ex. 1014, 11:20–22, Figs. 16, 17).

Patent Owner does not present an argument regarding claim 4. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches window 18 near the button end of housing 1 and helical rib 16 on an inner surface of housing 1, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 3, from which claim 4 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 4, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 4.

5. Analysis of Claim 5

Claim 5 depends from claim 1 and recites "wherein said driver comprises a cylindrical shape." Ex. 1003, 7:21–22.

Petitioner argues that "[d]river tube 85 is shown to have a cylindrical shape." Pet. 39 (citing Ex. 1011 ¶ 295; Ex. 1014, Fig. 17). As discussed above for claim 1, Petitioner argues that driver tube 85 of Steenfeldt-Jensen teaches the driver of claim 1. *Id.* at 29–30 (citing Ex. 1011 ¶¶ 273–276; Ex. 1014, 11:6–19, 12:4–12, Figs. 16, 17).

We find that Figure 17 of Steenfeldt-Jensen shows that driver tube 85 has a cylindrical shape. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 295 (citing Ex. 1014, Fig. 17).

Patent Owner does not present an argument regarding claim 5. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen shows driver tube 85 having a cylindrical shape, Petitioner persuades us that

Steenfeldt-Jensen teaches "wherein said driver comprises a cylindrical shape."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 5 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 5, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 5.

6. Analysis of Claim 6

Claim 6 depends from claim 1 and recites "wherein said dose knob extends circumferentially around at least a portion of said tubular clutch." Ex. 1003, 7:23–25.

Petitioner argues that "[f]lange 83 of bushing 82 sits within a compartment of dose-setting button 81" and that "[d]ose-setting button 81 thus extends circumferentially around a portion of bushing 82." Pet. 39–40 (citing Ex. 1011 ¶¶ 296–297; Ex. 1014, 11:20–51, Figs. 15–17). As discussed above for claim 1, Petitioner argues that dose setting button 81 of Steenfeldt-Jensen teaches the dose knob of claim 1. *Id.* at 25–26 (citing Ex. 1011 ¶¶ 266, 267; Ex. 1014, 11:22–25, 11:52–62, Figs. 15–17). Petitioner also argues that bushing 82 of Steenfeldt-Jensen teaches the tubular clutch of claim 1. *Id.* at 30–33 (citing Ex. 1011 ¶¶ 280–283; Ex. 1014, 11:26–42, 11:52–62, 12:1–13, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[a]t its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81" (Ex. 1014, 11:22–25), "bushing 82 ha[s] a flange 83 at its proximal end" (*id.* at 11:26), "[i]n the dose setting button a compartment is . . . provided with . . . a bottom with

a rosette of teeth having a triangular cross-section" (*id.* at 11:34–37), "flange 83 of the bushing 82 is adopted in said compartment" (*id.* at 11:37–38), and "[a]t its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment" (*id.* at 11:40–42). We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 266–267 (citing Ex. 1014, 11:22–25, 11:52–62, Figs. 15–17), 296–297 (citing Ex. 1014, Fig. 16).

Patent Owner does not present an argument regarding claim 6. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches that dose setting button 81 is circumferentially around bushing 82 when the rosettes of dose setting button 81 and bushing 82 are engaged, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said dose knob extends circumferentially around at least a portion of said tubular clutch."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 6 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 6, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 6.

7. Analysis of Claim 12

Claim 12 depends from claim 1 and recites "wherein said driver comprises at least one flange." Ex. 1003, 7:58–59.

Petitioner argues that "[d]river tube 85 includes a pawl formed as a flange at its needle-end." Pet. 40–41 (citing Ex. 1011 ¶¶ 298–300; Ex. 1014, 11:6–11, Figs. 15–17). As discussed above for claim 1, Petitioner argues that driver tube 85 of Steenfeldt-Jensen teaches the driver of claim 1. *Id.* at

29–30 (citing Ex. 1011 ¶¶ 273–276; Ex. 1014, 11:6–19, 12:4–12, Figs. 16, 17).

We find that Figure 17 of Steenfeldt-Jensen shows that driver tube 85 has a flange. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 298–299 (citing Ex. 1014, Fig. 17).

Patent Owner does not present an argument regarding claim 12. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen shows driver tube 85 has a flange, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said driver comprises at least one flange."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 12 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 12, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 12.

8. Analysis of Claim 13

Claim 13 depends from claim 12 and recites "wherein said at least one flange is located near a distal portion of said driver." Ex. 1003, 7:60–61.

Petitioner argues that "[d]river tube 85 includes a pawl formed as a flange at its needle-end." Pet. 40–41 (citing Ex. 1011 ¶¶ 298–300; Ex. 1014, 11:6–11, Figs. 15–17).

We find that Figure 17 of Steenfeldt-Jensen shows that the flange of driver tube 85 is at the needle-end. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 300 (citing Ex. 1014, Fig. 17).

Patent Owner does not present an argument regarding claim 13. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen shows the

flange of driver tube 85 is at the needle-end, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said at least one flange is located near a distal portion of said driver."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 12, from which claim 13 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 13, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 13.

9. Analysis of Claim 14

Claim 14 recites that the housing part of claim 1 "further compris[es] a clicker, said clicker providing at least an audible feedback to a user when said dose knob is rotated." Ex. 1003, 7:62–64.

Petitioner argues that "[f]lange 83 of bushing 82 includes radial protrusion 87, which drags over axial recesses on the compartment of dose-setting button 81 to produce clicks (audible feedback) when the user rotates dose-setting button 81." Pet. 41 (citing Ex. 1014, 11:34–40, 11:62–67), 44 (citing Ex. 1011 ¶¶ 301–302; Ex. 1014, 9:30–35, 9:48–50, 11:62–67).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[i]n the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses," "flange 83 of the bushing 82 is adopted in said compartment and has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment," and "by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one." Ex. 1014, 11:34–40, 11:62–67. We also credit

Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 301–302 (citing Ex. 1014, 11:34–40, 11:62–67, Fig. 17).

Patent Owner does not present an argument regarding claim 14. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches its injection syringe includes radial protrusion 87 that clicks when dose setting button 81 is rotated, Petitioner persuades us that Steenfeldt-Jensen teaches "a clicker, said clicker providing at least an audible feedback to a user when said dose knob is rotated."[8]

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 14 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 14, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 14.

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[8] Petitioner also argues that, if the means-plus-function interpretation for "clicker" applies, "Steenfeldt-Jensen teaches the same structure performing the same function." Pet. 45–46 (citing Ex. 1003, 5:57–59; Ex. 1011 ¶ 303; Ex. 1014, 11:34–42, 11:52–67); *see also id.* at 15–16 (proposing means-plus-function interpretation for "clicker") (citing Ex. 1003, 2:20–35, 4:33–48, 4:63–67, 5:1–5, 5:44–49, 5:51–57, 6:20–21, 6:36–43, Figs. 1, 5–10; Ex. 1028, 101–106, 112–116). We stated that the parties "may address this issue further during trial if necessary." Dec. to Inst. 15. Patent Owner did not address whether "clicker" is a means-plus-function term. *See* PO Resp. 9–13. We note that Petitioner fails to present any evidence or argument to overcome the presumption that "clicker," which does not recite the word "means," is not a means-plus-function limitation. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (when a claim limitation does not include the word "means," there is a presumption that the term is not a means-plus-function limitation and § 112, ¶ 6 does not apply); *see also* Ex. 2165, 22–23 (concluding in related litigation that defendants did not carry their burden of showing that "clicker" is a means-plus-function term).

10. Analysis of Claim 15

Claim 15 depends from claim 14 and recites "wherein said clicker provides tactile feedback to a user when said dose knob is rotated." Ex. 1003, 7:65–67.

Petitioner argues that one of ordinary skill in the art would have understood that the asserted clicker of Steenfeldt-Jensen also provides tactile feedback. Pet. 41–42 (citing Ex. 1014, 3:21–24), 44 (citing Ex. 1003, 5:54–60; Ex. 1011 ¶¶ 304–306; Ex. 1014, 3:21–24, 11:34–40, 11:62–67).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[a]ccording to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose" and that "by the rotation of the dose setting button 81 in any direction the radial protrusion 87 . . . will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one." Ex. 1014, 3:21–24, 11:62–67. We also credit Mr. Leinsing's testimony that one of ordinary skill in the art would have understood radial protrusion arm 87 provides a tactile feedback as it moves between recesses because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 304 (citing Ex. 1014, 3:21–27, Fig. 15–17)

Patent Owner does not present an argument regarding claim 15. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because one of ordinary skill in the art would have understood that Steenfeldt-Jensen teaches its radial protrusion 87 clicks and provides a tactile feedback when dose setting button 81 is rotated, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said clicker provides tactile feedback to a user when said dose knob is rotated."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 14, from which claim 15 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 15, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 15.

11. Analysis of Claim 16

Claim 16 depends from claim 14 and recites "wherein said clicker provides audible feedback when said dose knob is rotated in a dose increasing direction." Ex. 1003, 8:1–3.

Petitioner argues that one of ordinary skill in the art "would have understood that audible feedback would be provided in both a dose-increasing direction and a dose-decreasing direction." Pet. 42 (citing Ex. 1014, 11:62–67), 44 (citing Ex. 1011 ¶¶ 307–309; Ex. 1014, 11:62–67).

We find that the relied-upon portion of Steenfeldt-Jensen teaches that "by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one." Ex. 1014, 11:62–67. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 307–308 (citing Ex. 1014, 11:62–67).

Patent Owner does not present an argument regarding claim 16. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches that radial protrusion 87 clicks when dose setting button 81 is rotated "in any direction," Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said clicker provides audible feedback when said dose knob is rotated in a dose increasing direction."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 14, from which claim 16 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 16, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 16.

12. Analysis of Claim 17

Claim 17 depends from claim 14 and recites "wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction." Ex. 1003, 8:4–6.

Petitioner relies on its arguments for claims 14–16 (Pet. 42) and argues that one of ordinary skill in the art "would have understood that audible feedback would be provided in both a dose-increasing direction and a dose-decreasing direction" (*id.* at 44 (citing Ex. 1011 ¶¶ 307–309; Ex. 1014, 11:62–67)).

We find that the relied-upon portion of Steenfeldt-Jensen teaches that "by the rotation of the dose setting button 81 in any direction the radial protrusion 87 . . . will click." Ex. 1014, 11:62–67. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 309.

Patent Owner does not present an argument regarding claim 17. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches that radial protrusion 87 clicks when dose setting button 81 is rotated "in any direction," Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 14, from which claim 17 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 17, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 17.

13. Analysis of Claim 18

Claim 18 recites:

> The housing part of claim 14, wherein said clicker comprises,
>
> at least one flexible arm, said flexible arm comprising at least one tooth member, and
>
> at least one spline,
>
> wherein when said dose knob is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

Ex. 1003, 8:7–15.

Petitioner relies on its arguments for claims 14–16, Figure 17 of Steenfeldt-Jensen, and paragraph 310 of declarant testimony. Pet. 42–43. Petitioner also argues that one of ordinary skill in the art "would have understood protrusion 87 is a 'flexible arm' with a 'tooth member' at its tip for deforming and dragging into the recesses" and that "the recesses to form ridges or splines therebetween." *Id.* at 45 (citing Ex. 1011 ¶¶ 310–312; Ex. 1014, 11:34–42).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[i]n the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses" and that "flange 83 of the bushing 82 . . . has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment." Ex. 1014, 11:34–

40. As discussed for claim 14, we find that Steenfeldt-Jensen teaches that "by the rotation of the dose setting button 81 in any direction the radial protrusion 87 . . . will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one." *Id.* at 11:62–67. We also find that Figure 17 of Steenfeldt-Jensen shows radial protrusion 87 with a tooth member.

We further credit Mr. Leinsing's testimony that one of ordinary skill in the art would have understood radial protrusion 87 is a flexible arm with a tooth member that deforms and drags over recesses because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 310–311 (citing Ex. 1014, 11:34–42, 11:62–67, Fig. 17). We additionally credit Mr. Leinsing's testimony that one of ordinary skill in the art would have understood that the recesses of dose setting button 81 teach the splines of claim 18. Ex. 1011 ¶ 311 (citing Ex. 1014, 11:34–42, 11:62–67, Fig. 17).

Patent Owner does not present an argument regarding claim 18. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because one of ordinary skill in the art would have understood that Steenfeldt-Jensen teaches radial protrusion 87 is a flexible arm with a tooth member that deforms and drags over the recesses of dose setting button 81 to click, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 18.

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 14, from which claim 18 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 18, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 18.

14. Analysis of Claim 20

Claim 20 recites:

> The housing part of claim 14, wherein
>
> said clicker generally comprises a cylindrical shape having a first and a second end, and
>
> said cylindrical shape is provided at said first end with at least one flexible extending arm.

Ex. 1003, 8:19–23.

Petitioner argues that "protrusion 87 is part of cylindrical flange 83" and that "[f]lange 83 has first (button-end) and second (needle-end) ends, with flexible protrusion 87 extending along its length and thus 'provided at' flange 83's button-end." Pet. 43 (citing Ex. 1011 ¶ 313; Ex. 1014, Fig. 17), 45 (citing Ex. 1011 ¶¶ 313–314; Ex. 1014, Figs. 15–17).

We find that Figure 17 of Steenfeldt-Jensen shows radial protrusion 87 as part of flange 83 of bushing 82. We also find that Figure 17 shows flange 83 has a cylindrical shape with two ends and radial protrusion 87 is between those ends. We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 313 (citing Ex. 1014, Fig. 17).

Patent Owner does not present an argument regarding claim 20. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen shows radial protrusion 87 between two ends of a cylindrical flange 83, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said clicker generally comprises a cylindrical shape having a first and a second end, and said cylindrical shape is provided at said first end with at least one flexible extending arm."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 14, from which claim 20 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 20, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches the limitations of claim 20.

15. Analysis of Claim 23

Claim 23 depends from claim 1 and recites "wherein said piston rod comprises a generally circular cross section." Ex. 1003, 8:33–34.

Petitioner argues that Steenfeldt-Jensen teaches the piston rod of claim 23 and that one of ordinary skill in the art would have understood that the piston rod of Steenfeldt-Jensen has a generally circular cross section. Pet. 46–48 (citing Ex. 1011 ¶¶ 315–316; Ex. 1014, 5:61–65, 11:15–19, Figs. 15–17).

We find that Figure 16 of Steenfeldt-Jensen shows that piston rod 6 has "a circular cross-section at both its button-end (non-threaded, circular portion) and needle-end (circular portion fitting into pressure foot 9)," as asserted by Petitioner (*see* Pet. 47 (citing Ex. 1011 ¶ 316; Ex. 1014, 5:61–65, Figs. 15–17)). We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 315–316 (citing Ex. 1014, 5:61–65, Figs. 15–17).

Patent Owner does not present an argument regarding claim 23. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen shows piston rod 6 includes a portion with a generally circular cross section, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said piston rod comprises a generally circular cross section."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 23 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 23, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 23.

16. Analysis of Claim 26

Claim 26 depends from claim 1 and recites "wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing." Ex. 1003, 8:43–45.

Petitioner refers to its arguments for the dose dial sleeve and wherein clause of claim 1 and argues that "scale drum 80 is provided outside bushing 82 and radially inward of housing 1." Pet. 48–49 (citing Ex. 1011 ¶ 319; Ex. 1014, Fig. 16).

We find that Figure 16 of Steenfeldt-Jensen shows that "scale drum 80 is provided outside bushing 82 and radially inward of housing 1," as asserted by Petitioner (*see* Pet. 49 (citing Ex. 1011 ¶ 319)). We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 319 (citing Ex. 1014, Fig. 16).

Patent Owner does not present an argument regarding claim 26. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen shows scale drum 80, the asserted dose dial sleeve, outside bushing 82, the asserted clutch, and within housing 1, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 26

depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 26, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches the limitations of claim 26.

17. Analysis of Claim 27

Claim 27 depends from claim 1 and recites "wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along an outer surface of said dose dial sleeve." Ex. 1003, 8:46–49.

Petitioner refers to arguments presented for the main housing and dose dial sleeve of claim 1. Pet. 50. Petitioner also argues that "[h]ousing 1 includes helical rib 16, which sits in a helical groove on the outer surface of scale drum 80." *Id.* at 50 (citing Ex. 1011 ¶ 321; Ex. 1014, 11:20–22, Fig. 16), 51 (citing Ex. 1011 ¶ 320; Ex. 1014, 11:20–22, Fig. 16).

We find that a relied-upon portion of Steenfeldt-Jensen teaches that "scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib 16 along the inner wall of the housing 1." Ex. 1014, 11:20–22. We also find that Figure 16 of Steenfeldt-Jensen shows "[h]ousing 1 includes helical rib 16, which sits in a helical groove on the outer surface of scale drum 80," as asserted by Petitioner (*see* Pet. 51 (citing Ex. 1011 ¶ 320; Ex. 1014, 11:20–22, Fig. 16)). We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 320 (citing Ex. 1014, 11:20–22).

Patent Owner does not present an argument regarding claim 27. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches housing 1 has helical rib 16 that engages a helical track of scale drum 80, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said main

housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along an outer surface of said dose dial sleeve."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 27 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 27, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 27.

18. Analysis of Claim 28

Claim 28 depends from claim 27 and recites "wherein said helical rib extends for at least a single sweep of said inner surface of said main housing." Ex. 1003, 8:50–52.

Petitioner refers to arguments presented for the main housing and dose dial sleeve of claim 1. Pet. 50. Petitioner also argues that "FIGS. 15–16 show helical rib 16 extends for multiple sweeps along the internal surface of housing 1." *Id.* at 51 (citing Ex. 1011 ¶ 321; Ex. 1014, 11:20–22, Fig. 16), 51 (citing Ex. 1011 ¶ 321).

We find that "FIGS. 15–16 show helical rib 16 extends for multiple sweeps along the internal surface of housing 1," as asserted by Petitioner (*see* Pet. 51 (citing Ex. 1011 ¶ 321)). We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 321 (citing Ex. 1014, Fig. 16).

Patent Owner does not present an argument regarding claim 28. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen shows that helical rib 16 of housing 1 extends for at least one sweep, Petitioner

persuades us that Steenfeldt-Jensen teaches "wherein said helical rib extends for at least a single sweep of said inner surface of said main housing."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 27, from which claim 28 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 28, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 28.

19. Analysis of Claim 29

Claim 29 depends from claim 27 and recites "wherein said helical rib comprises a single start helical rib." Ex. 1003, 8:53–54.

Petitioner refers to arguments presented for the main housing and dose dial sleeve of claim 1. Pet. 50. Petitioner also argues that one of ordinary skill in the art "would have understood helical rib 16 to be a 'single start helical rib,'" "would have understood mechanical differences between single-start and multi-start threads, and been aware that single-start threads were the predominant type of thread in this context." *Id.* at 51 (citing Ex. 1011 ¶¶ 241–244, 322–325). Petitioner further points to "Steenfeldt-Jensen's reference to rib, singular" and description of "the rib as having "'a high pitch.'" Pet. 51 (citing Ex. 1011 ¶ 324; Ex. 1014, 6:7–17).

We find that the relied-upon portion of Steenfeldt-Jensen teaches that "[o]n the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch." Ex. 1014, 6:7–17. We agree with Petitioner and find that one of ordinary skill in the art "would have understood helical rib 16 to be a 'single start helical rib.'" Pet. 51 (citing Ex. 1011 ¶¶ 241–244, 322–325; Ex. 1014, 6:7–17). We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen

supports it. Ex. 1011 ¶¶ 241–244 (citing Ex. 1005, 3:56–67 (Veasey '008 patent regarding axial distance)), 322–325 (citing Ex. 1014, 6:7–17, 11:20–22, 11:52–54, 12:4–9, Figs. 15–17).

Patent Owner does not present an argument regarding claim 29. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches that helical rib 16 has a high pitch and so one of ordinary skill in the art would have understood helical rib 16 to be a single start helical rib, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said helical rib comprises a single start helical rib."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 27, from which claim 29 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 29, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 29.

20. Analysis of Claim 30

Claim 30 depends from claim 1 and recites "wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove." Ex. 1003, 8:55–57.

Petitioner argues that "[i]n another, similar embodiment, Steenfeldt-Jensen describes saw tooth 91 at a button-end of the scale drum, which abuts tooth 92 on the bushing's needle-end to stop rotation of the drum." Pet. 52–53 (citing Ex. 1014, 9:57–62, Figs. 12, 13); *see also id.* at 51–52 (citing Ex. 1014, 9:57–62, Figs. 12, 13, 15–17). According to Petitioner, one of ordinary skill in the art "would have understood from Steenfeldt-Jensen that the tooth 91 acts as a 'radial stop' to limit the length of travel of the scale drum and thus set the maximum dose for a single injection." *Id.* at 53 (citing

Ex. 1011 ¶¶ 326–327). Petitioner also argues that one of ordinary skill in the art: (1) "would have understood Steenfeldt-Jensen as teaching the use of a 'radial stop' near an end of the drum's helical drum to limit the drum's length of travel during dose-setting," (2) "would have expected a radial stop, such as a protruding tooth, to be provided near the needle-end of scale drum 80, since it is this end that reaches the button-end of the housing when a maximum dose is set," and (3) "would have understood that such a stop would serve the same purpose as the stop of FIGS. 11–13 and operate analogously by preventing further drum movement to indicate that the maximum set dose had been reached." *Id.* (citing Ex. 1011 ¶¶ 328–332; Ex. 1014, Figs. 15–17).

Patent Owner responds that "Steenfeldt-Jensen already includes a mechanism on driver tube 85 that serves as a radial stop" and outer hooks 86 of driver tube 85 that abut against the needle-end of longitudinal slot 84 of bushing 82, when the dose scale drum 80 is fully dialed out, prevent further movement. PO Resp. 47–48 (citing Pet. 51–53; Ex. 1011 ¶¶ 327, 329; Ex. 2107 ¶¶ 258–260). Patent Owner argues that "adding a radial stop to the dose scale drum 80 of Steenfeldt-Jensen's fifth embodiment would not serve any additional purpose" and "Petitioner's expert is unable to explain why a POSA would have decided to add a radial stop, as allegedly taught by the 'saw tooth 91' of Steenfeldt-Jensen's third embodiment, to dose scale drum 80." *Id.* at 49 (citing Ex. 2107 ¶ 259).

Patent Owner also responds that Mr. Leinsing has not explained how saw tooth 91 at the button-end of the third embodiment would have been implemented at the needle-end of the fifth embodiment. *Id.* at 49–50 (citing Pet. 53; Ex. 1011 ¶ 329). Patent Owner contends that the fifth embodiment must be widened because it "does not have any space for a pair of protruding

teeth, or other stops, between the dose scale drum 80 . . . and housing 1." *Id.* at 50–51 (citing Ex. 1014, Fig. 15; Ex. 2107 ¶ 261; Ex. 2163, 169:12–170:20). Patent Owner also contends that one of ordinary skill in the art would not have added a stop on housing 1 near the button-end to engage a stop near the needle-end of dose scale drum 80 because dose scale drum 80 "would screw out past window 18 of the housing—*i.e.*, well past its maximum dosage." PO Resp. 52–53 (citing Ex. 1011 ¶ 329; Ex. 1014, Fig. 15; Ex. 2107 ¶ 262).

Petitioner replies that Patent Owner concedes unpatentability because Patent Owner "appears to state that no modification is necessary . . . because it identifies outer wall hooks 86 that would be 'near' the distal end of the dose-scale drum 80 (and its groove), when the drum is at its maximum dose setting." Pet. Reply 18. Petitioner also replies that "Steenfeldt-Jensen offering two known solutions to the same problem does not make the teaching of one solution in one embodiment unobvious to use in another embodiment." Pet. Reply 18 (citing *KSR*, 550 U.S. at 421).

Petitioner argues that "Steenfeldt-Jensen teaches a stop to limit the travel of the dose-scale drum is desirable," the "projecting tooth would have been on the end of the drum in the direction to be limited," "the third embodiment provides a suggestion that applies equally to the fifth embodiment's drum," the "third embodiment blocks the same rotation using pawl 13's engaging member 40," and "Steenfeldt-Jensen provides a [person of ordinary skill in the art] ample guidance on modifying the fifth embodiment for a similar result." *Id.* at 18–19 (citing Pet. 52–53; Ex. 1011 ¶ 328; Ex. 1014, 9:36–42, 9:57–62; Ex. 1095 ¶ 80).

Petitioner also argues that Patent Owner "ignores the express teachings of Steenfeldt-Jensen as a whole," does not credit ordinary

creativity, and erroneously argues that one of ordinary skill in the art would fail to place stops near the button-end of the rib and the needle-end of the drum so as to stop the drum before the maximum dose. *Id.* at 19 (citing PO Resp. 52; Ex. 1095 ¶¶ 80–81). Petitioner further argues that Patent Owner concedes the proposed modification can be done, because Patent Owner argues the pen must be widened. *Id.* at 19–20 (citing PO Resp. 49–50). Petitioner asserts that wider pens exist, wider pens facilitate gripping, the figures should not be relied upon for dimensions, and teeth 91, 92 fit between drum 17 and bushing 53 of Steenfeldt-Jensen's third embodiment. *Id.* at 20 (citing Ex. 1048 ¶ 50; Ex. 1095 ¶ 81).

Patent Owner replies that "the claim requires that the *dose dial sleeve* includes the radial stop and the hooks 86 and slot 84 are not part of the dose dial sleeve in the fifth embodiment" and that "Petitioner[] concede[s] that the hooks 86 and slot 84 provide a maximum dose stop." PO Sur-reply 12 (citing PO Resp. 47; Pet. Reply 18; Ex. 1011 ¶ 329; Ex. 2164, 271:7–16). Patent Owner also argues that "nowhere does Steenfeldt-Jensen discuss 'axial play' issues caused by the hooks 86 and slot 84" and Petitioner provides no argument that the fifth embodiment would be modified "to have a completely different maximum dose stop rather than address the play in the hooks-and-slot." *Id.* at 13 (citing Pet. Reply 18; Ex. 2164, 271:13–16).

As for the replacement of hooks and slot with pawl 13, Patent Owner replies that (1) there is no support and mere attorney argument, (2) Petitioner does not explain how to modify the fifth embodiment with the pawl, (3) the pawl is not analogous to the hooks and slot because the hooks and slot do not permit axial movement when the maximum dose is dialed, and (4) one of ordinary skill in the art would not have been motivated to make the modification because it would widen the pen. *Id.* (citing PO Resp. 47, 50;

Pet. Reply 19). Patent Owner argues that Petitioner does not dispute that the pen would be wider, which is not desirable. *Id.* at 14 (citing Pet. Reply 20; Ex. 2163, 169:12–170:20; Ex. 2107 ¶ 261).

We find that the relied-upon portion of Steenfeldt-Jensen teaches:

> When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

Ex. 1014, 9:57–62. We also credit Mr. Leinsing's testimony regarding saw tooth 91 because the record supports it. Ex. 1011 ¶¶ 326–327 (citing Ex. 1014, 8:63–67, 9:36–46, 9:52–62, Figs. 11–13). Steenfeldt-Jensen also supports Mr. Leinsing's testimony that dose scale drum 17 includes a helical groove on its outer surface. *Id.* ¶ 326; Ex. 1014, 9:52–56.

Patent Owner does not dispute that Steenfeldt-Jensen teaches saw tooth 91 on a dose scale drum that abuts tooth 92 (*see* PO Resp. 47–53) and instead argues that saw tooth 91 of the third embodiment would be redundant in view of the radial stop of the fifth embodiment. *Id.* at 48 ("Thus, adding a radial stop to the dose scale drum 80 of Steenfeldt-Jensen's fifth embodiment would not serve any additional purpose.").

Patent Owner, thus, indicates, and we agree, that the fifth embodiment has a "radial stop." *Id.* at 47 ("Steenfeldt-Jensen already includes a mechanism on driver tube 85 that serves as a radial stop."); *see also* Pet. Reply 18; Ex. 1011 ¶ 330 ("The hooks 86 may serve as a stop by engaging the end of slots 84 when the bushing 82 axially retracted by its maximum length during dose setting."); Ex. 2107 ¶ 258 ("Steenfeldt-Jensen already includes a mechanism on driver tube 85 that serves the alleged purpose of a radial stop."). Figures 15 and 16 of Steenfeldt-Jensen show that hooks 86

and slots 84 are near a distal end of the helical track of scale drum 80. Above for claim 1, we find that, because Steenfeldt-Jensen teaches that scale drum 80 has a helical track on its outer surface that engages helical rib 16 of housing 1, Steenfeldt-Jensen teaches "a dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing." The full record, thus, persuades us that Steenfeldt-Jensen's third and fifth embodiments teach a radial stop on or near a dose dial sleeve with a helical groove.

Turning to Petitioner's reason for modifying Steenfeldt-Jensen's fifth embodiment with the teeth arrangement of the third embodiment, because the full record persuades us that the arrangement of teeth 91, 92 of the third embodiment and hooks 86 and slots 84 of the fifth embodiment both serve as radial stops (Ex. 1011 ¶¶ 328–330; Ex. 2107 ¶ 258), we agree with Mr. Leinsing that a "person of ordinary skill would have understood that either could be used as a stop to set a desired maximum length of travel of the scale drum 80 during dose setting" (Ex. 1011 ¶ 330). Steenfeldt-Jensen also supports Mr. Leinsing's testimony that "the use of a stop near an end of the drum's helical groove to set a certain length of travel was a well-known, routine and predictable way to limit the length of axial travel of a component." Ex. 1011 ¶ 330; Ex. 1014, 9:36–42, 9:57–62. Thus, the full record persuades us that the radial stops of the third and fifth embodiments are interchangeable and one of ordinary skill in the art could have implemented either with a reasonable expectation of success. *KSR*, 550 U.S. at 421.

Even if Petitioner's proposed modification results in a wider pen, we agree with Petitioner that it does not undermine making the modification because the record contains evidence that a wider pen is not a disadvantage

when trying to facilitate gripping. Pet. Reply 18; Ex. 1048 ¶ 50; Ex. 1095 ¶ 81. Steenfeldt-Jensen does not indicate that its third embodiment, which includes teeth 91, 92, has any issues with width. Ex. 1014, 8:34–10:13 (description of the third embodiment); Ex. 1095 ¶ 81.

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 30 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 30, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 30, and that one of ordinary skill in the art would have had a reason to modify the fifth embodiment of Steenfeldt-Jensen with a reasonable expectation of success.

21. Analysis of Claim 32

Claim 32 depends from claim 30 and recites "wherein said radial stop is positioned near a distal end of said helical groove." Ex. 1003, 8:64–65.

The parties provide the same arguments for claim 32 that are summarized above for claim 30. *See* Pet. 51–53; PO Resp. 47–54; Pet. Reply 18–20; PO Sur-reply 12–14.

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 30, from which claim 32 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claims 1 and 30, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 32, and that one of ordinary skill in the art would have had a reason to modify the fifth embodiment of Steenfeldt-Jensen with a reasonable expectation of success.

22. Analysis of Claim 33

Claim 33 depends from claim 1 and recites "wherein if a user inadvertently dials said dose knob in one direction beyond a desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced." Ex. 1003, 8:66–9:2.

Petitioner refers to its arguments for the dose knob of claim 1 and argues that "Steenfeldt-Jensen teaches that, if a user inadvertently dials a set dose beyond what is desired, it may be reduced by rotating button 81 in the opposite direction." Pet. 53–54 (citing Ex. 1011 ¶ 333; Ex. 1014, 1:20–22, 11:52–65).

We find that a relied-upon portion of Steenfeldt-Jensen teaches "a dose is set by rotating the dose setting button 81 in a clockwise direction" and "a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction." Ex. 1014, 11:52–53, 11:57–58. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 333 (citing Ex. 1014, 11:52–65).

Patent Owner does not present an argument regarding claim 33. *See* PO Resp. 30–54; PO Sur-reply 1–14. Because Steenfeldt-Jensen teaches setting a dose by rotating dose setting button 81 clockwise and reducing a set dose by rotating dose setting button 81 in the opposite direction, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein if a user inadvertently dials said dose knob in one direction beyond a desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 33 depends. Based on the full record before us and our findings from

Steenfeldt-Jensen regarding the limitations of claim 33, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 33.

23. Analysis of Claim 36

Claim 36 depends from claim 1 and recites "wherein said housing part and said container comprises a disposable device." Ex. 1003, 9:19–20.

Petitioner argues that "Steenfeldt-Jensen describes the device as having a fluid 'container' in the form of an ampoule" and "recognizes it was known to manufacture similar devices to be disposable," so that one of ordinary skill in the art would have known to manufacture a disposable device. Pet. 54–55 (citing Ex. 1011 ¶ 334; Ex. 1014, 1:22–29, 5:33–35, 12:10–13, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach "a syringe which is disposed of when the cartridge is empty" (Ex. 1014, 1:24–25), "injection syringe of the kind by which a liquid from an ampoule can be apportioned" (*id.* at 5:33–34), and "ampoule 89 in the ampoule holder 2" (*id.* at 12:13). Figures 15–17 show ampoule 89 in housing 1. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 334 (citing Ex. 1014, 1:24–26, 5:33–35, 12:10–13, Figs. 15–17).

Patent Owner does not present an argument regarding claim 36. *See* PO Resp. 30–54. Because Steenfeldt-Jensen teaches housing 1, disposable syringes, and syringes with ampoules, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said housing part and said container comprises a disposable device."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 36 depends. Based on the full record before us and our findings from

Steenfeldt-Jensen regarding the limitations of claim 36, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 36.

24. Analysis of Claim 38

Claim 38 depends from claim 1 and recites "further comprising an insert, said insert provided at a distal end of the main housing, said insert secured against rotation." Ex. 1003, 9:23–25.

Petitioner argues that "Steenfeldt-Jensen describes member 40, which is positioned near the housing's needle-end, is secured against rotation and longitudinal motion relative to the housing." Pet. 55–56 (citing Ex. 1011 ¶¶ 335–337; Ex. 1014, 5:55–58, 8:35–42, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that the "end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4" (Ex. 1014, 5:55–56), "end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing" (*id.* at 8:35–37), and "member 40 has at its periphery longitudinal recesses 43 which are engaged by not shown internal ribs in the housing to lock the member 40 against rotation relative to the housing 1" (*id.* at 8:39–42). We also find that Figures 15–17 of Steenfeldt-Jensen show member 40 at an end of housing 1. We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 335–336 (citing Ex. 1014, 8:35–42, Figs. 15–17).

Patent Owner does not present an argument regarding claim 38. *See* PO Resp. 30–54. Because Steenfeldt-Jensen teaches that member 40 is at the end of housing 1 and that member 40 is locked against rotation, Petitioner persuades us that Steenfeldt-Jensen teaches "an insert, said insert

provided at a distal end of the main housing, said insert secured against rotation."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 38 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 38, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 38.

25. Analysis of Claim 39

Claim 39 depends from claim 1 and recites "further comprising an insert, said insert provided at a distal end of the main housing, and said insert secured against longitudinal motion." Ex. 1003, 9:26–28.

Petitioner argues that "Steenfeldt-Jensen describes member 40, which is positioned near the housing's needle-end, is secured against rotation and longitudinal motion relative to the housing." Pet. 55–56 (citing Ex. 1011 ¶¶ 335–337; Ex. 1014, 5:55–58, 8:35–42, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that the "end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4" (Ex. 1014, 5:55–56), "end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing" (*id.* at 8:35–37), and "the member 40 having protrusions 41 engaging slots 42 in the housing to lock the member 40 to the housing 1" (*id.* at 8:37–39). We also find that Figures 15–17 of Steenfeldt-Jensen show member 40 at an end of housing 1. We further credit Mr. Leinsing's testimony that a "person of ordinary skill would have understood that the protrusions 41 served to secure the insert against longitudinal motion

relative to the housing" because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 337 (citing Ex. 1014, 8:37–39, Figs. 13, 17).

Patent Owner does not present an argument regarding claim 39. *See* PO Resp. 30–54. Because Steenfeldt-Jensen teaches that member 40 is at the end of housing 1 and because one of ordinary skill in the art would have understood that member 40 is locked against longitudinal motion relative to housing 1, Petitioner persuades us that Steenfeldt-Jensen teaches "an insert, said insert provided at a distal end of the main housing, and said insert secured against longitudinal motion."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claim 1, from which claim 39 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 39, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 39.

26. Analysis of Claim 40

Claim 40 depends from claim 39 and recites "wherein said insert comprises an opening extending therethrough, such that said piston rod is configured to extend through said opening." Ex. 1003, 9:29–31.

Petitioner argues that "[m]ember 40 includes an opening through which piston rod 6 extends," which would also be included in the proposed modification. Pet. 55–56 (citing Ex. 1011 ¶¶ 335, 338; Ex. 1014, 5:55–58, 8:35–42, Figs. 16, 17).

We find that a relied-upon portion of Steenfeldt-Jensen teaches that the "end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5" and "piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through

said bore." Ex. 1014, 5:55–58. We also credit Mr. Leinsing's testimony that a "person of ordinary skill would have understood that the member 40 includes a central bore through which the piston rod 6 extends" because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 338.

Patent Owner does not present an argument regarding claim 40. *See* PO Resp. 30–54. Because Steenfeldt-Jensen teaches that member 40 includes a central bore through which piston rod 6 extends, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said insert comprises an opening extending therethrough, such that said piston rod is configured to extend through said opening."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen teaches the limitations of claims 1 and 39, from which claim 40 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 40, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen teaches all the limitations of claim 40.

F. Objective Indicia of Nonobviousness

Patent Owner argues that the claimed inventions of the '486 patent "are embodied in the SoloSTAR® pen that was released in 2007 and has been a significant commercial success." PO Resp. 1. According to Patent Owner, "secondary indicia of non-obviousness confirm that the challenged claims of the 486 Patent are not obvious" and "Sanofi's SoloSTAR® pen injector, which practices claim 1 of the '486 Patent, satisfied a long-felt need in the industry for an easy-to-use, disposable pen that administered a long acting insulin or insulin analog" and the "improved ease-of-use provided by the pen injector design of the '486 Patent contributed directly to the

overwhelming commercial success of SoloSTAR®." *Id.* at 2 (citing Ex. 2101 (article reviewing various injection pens)).

1. Background

Patent Owner sold an insulin glargine solution administered as a once-daily subcutaneous injection for patients diagnosed with either Type 1 or Type 2 diabetes under the tradename Lantus® in three different forms. Ex. 2109 ¶¶ 6, 17. The first form launched in the United States in 2001 as "Lantus® vial" and is administered through a syringe. *Id.* ¶¶ 6, 18. The second form launched in the United States in 2005 in a pen injector form as "Lantus® OptiClik®," but was subsequently discontinued and allegedly did not practice the '486 patent. *Id.* ¶¶ 19, 36; Ex. 2107 ¶¶ 644–648. The third form launched in the United States in 2007 in a pen injector form as "Lantus® SoloSTAR®." Thereafter, in addition to Lantus®, a "long-acting insulin analog," Patent Owner also sold "fast-acting" injectable insulin with the SoloSTAR® pen injector, including Apidra® SoloSTAR® and Admelog® SoloSTAR®. *Id.* ¶¶ 6, 17, 22; Ex. 1048 ¶ 39. Patent Owner also explains that at the time of the invention of the '486 patent "there were already several pen-type injectors known in the art," including the commercially available Novo Nordisk FlexPen® which "closely corresponds" to an embodiment described in Steenfeldt-Jensen and which was marketed for administering an insulin analog as the "Levemir® FlexPen®." PO Resp. 2 (citing Ex. 1014, Figs. 1–17; Ex. 2107 ¶ 28), 71, 77.

2. SoloSTAR® and Claim 1

Patent Owner argues that "Sanofi's SoloSTAR® product practices claim 1 of the '486 Patent" and Patent Owner's declarant "confirms that the claimed components and interfaces, such as the threaded engagements, piston rod, driver, and tubular clutch, are reflected in the LANTUS®

SoloSTAR®." PO Resp. 70 (internal footnote omitted) (citing Ex. 2107 ¶¶ 513–550, 650).

Patent Owner's contention is persuasively supported by Dr. Slocum's unrebutted testimony that the SoloSTAR® pen injector practices claim 1 of the '486 patent. Ex. 2107 ¶ 513–550; *see id.* ¶ 513 (stating that "it is my opinion that the SoloSTAR® device practices at least claim 1 of the '486 patent"). Accordingly, based on Dr. Slocum's testimony, Patent Owner shows that SoloSTAR® practices claim 1 of the '486 patent.

Patent Owner, however, does not focus its arguments of objective evidence of nonobviousness on SoloSTAR® alone (with the exception of industry praise), but instead proceeds to argue that "Sanofi's Lantus® SoloSTAR® practices claim 1" of the '486 patent. PO Resp. 70 (footnote omitted). Importantly, none of the challenged claims of the '486 patent recite Lantus® or any other medication as a required limitation. Presumably, Patent Owner implicitly reasons that because SoloSTAR®, a pen injector for administering a medication, practices the challenged claims, the same pen injector sold as a combination product with medication, Lantus®, necessarily also practices the claimed invention. Petitioner does not dispute Patent Owner's contention and we are persuaded that Lantus® SoloSTAR® practices claim 1 of the '486 patent for the same reasons Patent Owner sufficiently established that SoloSTAR® practices the same claims.

As a brief summary of the legal standards we apply with regard to evidence of objective indicia of nonobviousness, we emphasize that such indicia are "only relevant to the obviousness inquiry 'if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].'" *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299,

1312 (Fed. Cir. 2006)). A patentee is entitled to a presumption of nexus "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))). If the patented invention is only a component of a commercially successful machine or process, the patentee is not entitled to a presumption of nexus. *Id.* (reaffirming the importance of the "coextensiveness" requirement). "[T]he purpose of the coextensiveness requirement is to ensure that nexus is only presumed when the product tied to the evidence of secondary considerations 'is the invention disclosed and claimed.'" *Id.* at 1374 (quoting *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)). "[T]he degree of correspondence between a product and a patent claim falls along a spectrum. At one end of the spectrum lies perfect or near perfect correspondence. At the other end lies no or very little correspondence." *Id.* "A patent claim is not coextensive with a product that includes a 'critical' unclaimed feature that is claimed by a different patent and that materially impacts the product's functionality." *Id.* at 1375.

Patent Owner does not argue that Lantus® SoloSTAR® is coextensive (or nearly coextensive) with any of the challenged claims, which do not require medication. Accordingly, to the extent that Patent Owner relies on evidence based on Lantus® SoloSTAR® to show objective indicia of nonobviousness, Patent Owner does not show that it is entitled to a presumption of nexus.

However, "[a] finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations." *Fox Factory*, 944 F.3d at 1375. "To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* at 1373–74 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). "Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention," meaning that "there must be a nexus to some aspect of the claim not already in the prior art." *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011) (emphasis in original). Additionally, there is no requirement that "objective evidence must be tied exclusively to claim elements that are not disclosed in a particular prior art reference in order for that evidence to carry substantial weight." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016). A patent owner may show, for example, "that it is the claimed combination as a whole that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly 'new' feature(s)." *Id*.

Patent Owner argues, as to the claimed invention of the '486 patent, that the components recited in the challenged claims "work together" to provide a device that is "easy to use" and that yields "a combination of desirable features and properties, such as (i) low injection force, (ii) short injection stroke length or higher maximum dose per injection, and (iii) a relatively small number of components that decrease the complexity of the device." PO Resp. 70 (citing Ex. 2107 ¶ 650).

The challenged claims do not require expressly any particular injection force, injection stroke, or dose per injection. *See* Ex. 1003, 6:59–7:12. Claim 1 recites a housing part comprising a main housing, dose dial sleeve, dose dial grip, piston rod, and drive sleeve, but it does not require any particular number of parts for the medication dispensing apparatus, much less a relatively small number of components. *See id.* The word "comprising" also indicates that additional components could be added to the ones expressly recited. *See id.* at 6:60. Claim 1 further requires the recited components to be in particular relative positions, such as "positioned within said housing," "disposed near," "provided within said housing," "extending along a portion of said piston rod," and "near a distal portion of said driver," but, other than threaded engagements between certain components, the challenged claim does not recite expressly how the components work together during injection. *See id.* at 6:63–7:7.

The alleged "features and properties" do not correspond to any recited limitation in any of the challenged claims. As Petitioner explains, Lantus® SoloSTAR® "is not 'the invention' of these claims," because "the claims do not require Lantus[®] (or insulin at all), an 80-unit cartridge, a particular stroke length or injection force." Pet. Reply 24. Moreover, Patent Owner offers no objective definition or explanation of what constitutes an "easy to use" pen injector, a "low injection force," a "short injection stroke length," a "higher maximum dose," or a "relatively small number of components."

Ultimately, the fact finder must weigh the secondary considerations evidence presented in the context of whether the claimed invention as a whole would have been obvious to a skilled artisan. *WBIP*, 829 F.3d at 1331–32. Once the patentee has presented a *prima facie* case of nexus, the burden of coming forward with evidence in rebuttal shifts to the challenger

"to adduce evidence to show that the commercial success was due to extraneous factors other than the patented invention." *Demaco*, 851 F.2d at 1393. Below we consider in more detail the evidence and argument provided by the parties with regard to any purported long-felt need, industry praise, and commercial success in light of the alleged nexus to the required features of the challenged claims of the '486 patent.

3. Long-Felt, Unmet Need

Patent Owner contends that, according to Dr. Goland's testimony, there was a "need [for] an easy-to-use injection device with a low injection force to reduce the burden on the patient and increase the likelihood of the patient adhering to their prescribed therapy." PO Resp. 71 (citing Ex. 2111 ¶¶ 22–26). Patent Owner also contends that available injection pens "had numerous shortcomings and design flaws that resulted in significant injection force" higher than SoloSTAR, and that "made the devices difficult to use and thus increased the risk of patients not adhering to their insulin and insulin-analog therapy." *Id.* at 71–72 (citing Ex. 2107 ¶ 646; Ex. 2109 ¶¶ 52–55; Ex. 2111 ¶¶ 23–25, 33–35; Ex. 2143 (article comparing patient preferences of injection pens); Ex. 2144 (article on dose accuracy in injection pens)). According to Patent Owner, SoloSTAR "revolutionized the injection pen market" because it was easier to use, as confirmed by literature at the time. *Id.* at 72–73 (citing Ex. 2111 ¶ 33; Ex. 2116, 7 (article on development of SoloSTAR)). Patent Owner asserts that the '486 patent addressed reducing overall force required for use, as reflected in a related patent; that industry recognized SoloSTAR solved the "problem of needing to deliver high doses with a short dial extension and with low injection force"; and that patients preferred SoloSTAR. *Id.* at 73–74 (citing Ex. 1003, 3:64–67; Ex. 1005, 1:66–2:3 (a drive mechanism "without having a

unidirectional coupling provides a valuable technical alternative" where reduced forced is necessary); Ex. 2117 (pen injection animation); Ex. 2121, 2, 9 (DBA Design Effectiveness Awards); Ex. 2123, 6 (article on dose accuracy in insulin glargine pens); Ex. 2128 (article on glargine and glulisine SoloSTAR pens); Ex. 2143; Ex. 2144; Ex. 2184, 2 (article promoting SoloSTAR pen); Ex. 2185, 1 (article on SoloSTAR's GOOD DESIGN Award)). Patent Owner, thus, asserts that SoloSTAR "satisfied a long-felt but unmet need for an easy-to-use pen that was particularly well suited to administer medication with a low injection force." *Id.* at 74.

a) Purported Evidence of Alleged Long-felt Need and Any Challenged Claim of the '486 Patent

There is no dispute that none of the challenged claims recite or otherwise require a low injection force, the ability to deliver high doses, or a short dial extension. Thus, to show that the challenged claims satisfied a long-felt, unmet need for an injection pen with these features, Patent Owner must show that the purported low injection force, ability to deliver high doses, and/or short dial extension is the direct result of the unique characteristics of the claimed invention. *Fox Factory*, 944 F.3d at 1373–74. Patent Owner does not carry this burden. The entirety of Patent Owner's argument and evidence on this specific issue consists essentially of the assertion that Dr. Slocum explained that "the inventions in the challenged claims describe a set of components that elegantly work together." PO Resp. 70 (citing Ex. 2107 ¶ 650); *see also id.* at 48 (stating that "due to the contributions of the above features described by" Dr. Slocum, "the Lantus® SoloSTAR® satisfied long-felt, but unresolved needs existing in commercially available pen injectors"); *see also* PO Sur-reply 24 (stating

that "the challenged claims enable SoloSTAR®'s low injection force and other features identified in the Response").

We have considered Dr. Slocum's testimony and find it insufficient to support Patent Owner's contentions. In his declaration, Dr. Slocum addressed how SoloSTAR® practices claims of *four different patents*, including the '486 patent. Ex. 2107 ¶¶ 439–649. Dr. Slocum then addresses in a single paragraph, reproduced below, the "Benefits of the Claims of the Challenged Patents":

> In my opinion, the claimed components and interfaces, such as the threaded engagements, piston rod, drive sleeves/driving members, dose stops, and clutch enable an injection device with (i) low injection force, (ii) short or long injection stroke length for low or high dose per injection, and (iii) a relatively small number of components that decrease the complexity and cost of the device. The arrangement of components limits the frictional losses in the mechanism, thereby providing an efficient force transmission from the user's hand to the injection piston in the ampoule that contains the medicament. The challenged claims also enable a device without a "resetting" operation, thereby making the injection pen easier to use. The challenged claims further enabled an injection device with a shorter dial extension, providing additional benefits for patients lacking dexterity. Specifically, the SoloSTAR® has a maximum of 80 units, while the FlexPen® only has a maximum of 60 units. While the SoloSTAR®'s dial would extend to 25.5mm to inject 60 units, the FlexPen® must extend to 33mm to inject 60 units. All of these features are evidenced in the SoloSTAR® injector pen which practices the inventions of the challenged claims. The embodiments described in the challenged patents also show that these advantages can be realized by a small number of components, thereby enabling a device that can be manufactured at lower cost. Also, because the pen is disposable, the components can be made of inexpensive materials, thereby further reducing the production costs.

Id. ¶ 650. Dr. Slocum does not explain which "claimed components and interfaces" of which patents he is specifically referring to among the four patents discussed in his declaration, and fails to address how any of the purported benefits are the "the direct result" of any "unique characteristics of the claimed invention." We agree with Mr. Leinsing that Dr. Slocum "provides no analysis as to how these claims supposedly enabled the benefits identified in paragraph 650 of his declaration, including low injection force, dose dial stroke length, and a small number of components." Ex. 1095 ¶ 156 (further explaining that "a person of ordinary skill would have understood that the components recited in the claims would not have necessarily provided any of these benefits, either alone or collectively," and "would have understood the claims as broadly including embodiments lacking all of these supposed benefits").

More critically, Dr. Slocum's opinion that some set of components recited in the '486 patent "enable an injection device" with certain features, such as "low injection force" is, on its face, insufficient to establish the necessary nexus. As we explained above, the evidence of secondary considerations, here the "low injection force," must be shown to be the "direct result of the unique characteristics of the claimed invention." *Fox Factory*, 944 F.3d at 1373–74 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). Merely "enabling" a "low injection force" means that the injection force may, or may not be "low," depending upon some other consideration, and, therefore, it is not "the direct result" of any claimed feature. In other words, setting aside the ambiguity of what constitutes a "low injection force," Patent Owner provides no evidence that a pen injector made in accordance with any challenged claim will necessarily result in a device with a "low injection force."

The same is true of the other purported benefits identified by Dr. Slocum. For example, Dr. Slocum states that some set of components recited in the '486 patent "enable an injection device" with "a relatively small number of components that decrease the complexity and cost of the device." The challenged claims do not require a "small number of components," and Patent Owner provides no evidence that a pen injector made in accordance with any challenged claim will necessarily result in a device with a "a relatively small number of components that decrease the complexity and cost of the device." Likewise, "injection stroke length" and "dose per injection" are unclaimed features purportedly "enabled," but not shown to be a "direct result" of any set of elements recited by any challenged claim. Thus, we find that Patent Owner fails to establish a nexus between the purported evidence of alleged long-felt need for a pen with a low or reduced injection force (or the ability to deliver high doses or a short dial extension) and any claim of the '486 patent at issue in this proceeding.

b) Patent Owner Fails to Show the Existence of a Long-felt, but Unresolved Need

Patent Owner does not show that a long-felt, but unresolved need existed at the time of the invention for "an easy-to-use pen that was particularly well suited to administer medication with a low injection force." *See* PO Resp. 74. The Federal Circuit has explained that "[l]ong-felt need is closely related to the failure of others," and that "[e]vidence] is particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand." *Eurand, Inc. v. Mylan Pharms., Inc.* (*In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*), 676 F.3d 1063, 1082 (Fed. Cir. 2012). Establishing a long-felt need requires objective

evidence that the invention has provided a long-awaited, widely accepted, and promptly adopted solution to a problem existent in the art, or that others had tried but failed to solve that problem. *See In re Mixon*, 470 F.2d 1374, 1377 (CCPA 1973). Furthermore, one must demonstrate that "widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem." *In re Allen*, 324 F.2d 993, 997 (CCPA 1963). Patent Owner's contentions and evidence fail to establish any failure of others, any unsatisfied demand, any long-awaited solution to a problem, or any other persuasive basis to show the existence of a long-felt need at the time of invention.

Patent Owner does not identify an objective means to measure or compare the ease of use of pen injectors to support the notion that a long-felt need existed for an "easy-to-use" injection device. *See* PO Resp. 70–74; PO Sur-reply 26–28. Dr. Goland suggests that "prior injection pen devices available prior to the launch of Lantus® SoloSTAR® were more difficult to use than Lantus® SoloSTAR® and had a higher injection force, meaning the devices required significantly more force by the patient's thumb to depress the button to administer the medication." Ex. 2111 ¶ 15. Dr. Goland does not quantify to what degree SoloSTAR® was easier to use and merely suggests that "[m]y patients overall prefer Lantus® SoloSTAR® over all other available pen injection devices." *Id.* ¶ 16; *see also id.* ¶¶ 27–30 (stating that OptiClik® "had a much higher injection force," that FlexPen® "has a relatively high injection force," and that "other devices suffered from the same shortcomings").

By contrast, Dr. Biggs highlights that "affordability" is more important to "ease of use" for patients than injection force, particularly in terms of patient adherence. Ex. 1048 ¶¶ 34, 35. Dr. Biggs states that

SoloSTAR® was "welcomed by Lantus® users as a significant improvement over Sanofi's defective OptiClik® pen but was not recognized as an unusually good pen in itself." *Id.* ¶ 43; *see also id.* ¶¶ 49, 50 (discussing reasons the OptiClik® pen was unsatisfactory). According to Dr. Biggs, "insulin drives the prescription, with the delivery mode being determined by the modes available from the prescribed insulin's manufacturer," and Lantus® SoloSTAR® "is prescribed frequently" because Lantus® "is a popular insulin," not because SoloSTAR® "is a remarkable pen." *Id.* ¶ 44. The notion of a long-felt need for an "easy-to-use" device is, at best, ambiguous in application. Dr. Goland, on behalf of Patent Owner, demonstrates the ambiguity and lack of objective evidence inherent in Patent Owner's argument by explaining that "the primary reason that the SoloSTAR® pen is so easy-to-use is because of the low injection force," but then stating that SoloSTAR® is "easier" because of a "short dial extension length," is "also easy to use because it includes the ability to dial up and dial back a desired dose, and provides tactile and audible feedback, portability, and ease of handling," has a "last dose stop" that "patients have found . . . contribute[s] to the device being easy to use," and is "disposable." Ex. 2111 ¶ 33–39. Patent Owner does not demonstrate any established measure of what constitutes a device that is "easy-to-use," but rather shows that there are many considerations that account for the ease of use of any device.

The evidence developed demonstrates that SoloSTAR® was not the first "easy to use" injection pen or that all of the competing pen injectors were not easy to use because they lacked a sufficiently "low" injection force. Patent Owner concedes that "[p]rior to the launch of Lantus® SoloSTAR®, there were multiple injection pens on the market for administering insulin or

an insulin analog – *e.g.*, Levemir® FlexPen® and Lantus® OptiClik® in the long-acting category, and the Humalog KwikPen in the rapid-and intermediate-acting categories, among many others." PO Resp. 49. Dr. Biggs also explains that other insulin pens were available and fungible with Lantus® SoloSTAR®. *See* Pet. Reply 26–27 (citing Ex. 1046, 9, 37, 39, 57, 62, 63, 75; Ex. 1048 ¶¶ 27, 29, 32–44–47, 51–53, 56; Ex. 2126, 1, 3; Ex. 2143, 1, 5, 9, 10, 70; Ex. 2145, 26). Dr. Biggs also persuasively establishes that "[a]vailable pens at the 2003 filing date were already considered "easy-to-use, convenient, and accurate." Ex. 1048 (citing Ex. 1046, 57, 62). Further, Petitioner establishes that:

- "other insulin pens were already considered easy to use both generally and for patients with special challenges like age or dexterity issues," (Pet. Reply 27 (citing Ex. 1048 ¶¶ 45–47, 52; Ex. 1046, 57, 62, 63)) [9];
- "Sanofi's studies confirm that both SoloSTAR® and FlexPen® were 'very easy to use,'" (*id.* (quoting Ex. 2145, 26); *see also id.* (citing Ex. 1048 ¶ 55; Ex. 2126, 1157 (stating that "the SoloSTAR® and FlexPen® were more user-friendly"); Ex. 2143, 650, 659 (stating that "both the SoloSTAR® pen and FlexPen® were found to have high patient usability"), 656 (stating that "the FlexPen® was also found to be user-friendly")));
- "Sanofi's studies concluded both the SoloSTAR® and FlexPen® were suitable in both elderly and younger patients and those with visual and dexterity impairments, and 'were associated

[9] Unless otherwise noted, citations rely on the pagination of the original document for articles and studies.

with comparable usability'" (*id.* (quoting Ex. 2126, 1159); *see also id.* (citing Ex. 1048 ¶ 56; Ex. 2143, 654, 658)); and that,

- SoloSTAR® was a "best-performing pen device *in a statistical tie with FlexPen*" (*id.* (quoting Ex. 2146, 9); *see also id.* (citing Ex. 1048 ¶ 52; Ex. 2146, 37, 39, 75)).

We find the evidence provided by Petitioner of no long-felt, unmet need discussed above more credible than Dr. Goland's insufficiently supported statement that "other pen devices . . . had too high of an injection force for my patients." *See* Ex. 2111 ¶ 42.

Patent Owner's evidence may demonstrate acceptance of Lantus® SoloSTAR® (*see, e.g.*, Ex. 2184, 1; Ex. 2185, 1; Ex. 2121, 6), but it does not show any failure of others, any unsatisfied demand, or any long-awaited solution to any problem. The mere fact that a pen injector with a lower injection force might, or might not, be preferable over other readily available and effective pen injectors, depending upon various considerations, including cost and medication, fails to show a long-felt, unmet need for a pen injector with a lower injection force. Accordingly, the evidence provided by Patent Owner does not demonstrate a long-felt need existed for an "easy-to-use" injection device corresponding to any of the features Patent Owner attributes to SoloSTAR®.

c) Patent Owner Fails to Show that Lantus® SoloSTAR® Satisfied a Purported Long-felt, but Unresolved Need

As discussed above, Patent Owner contends its product "satisfied a long-felt but unmet need for an easy-to-use pen that was particularly well suited to administer medication with a low injection force." PO Resp. 74. Given the ambiguity in Patent Owner's identification of any purported "long-felt, but unmet need," it is difficult to determine whether SoloSTAR®

met the need. What we can conclude is that Patent Owner does not show that the injection force of SoloSTAR® made it the easiest-to-use pen that was "particularly well suited to administer medication" invented at the time. Whether SoloSTAR® even provides a "low injection force" is in dispute and depends upon what study is relied upon and what other devices are compared.

Patent Owner relies on the opinions of Dr. Slocum and Dr. Goland, who, in turn, cite studies and internal marketing materials produced by Patent Owner to show that SoloSTAR® provides a reduced injection force, at least with respect to certain devices to which it was compared. PO Resp. 72; (citing Ex. 2111 ¶¶ 23–25; Ex. 2109 ¶¶ 52–55); *see also* Ex. 2111 ¶¶ 32, 33 (citing Ex. 2116, 9; Ex. 2123, 6; Ex. 2143, 7; Ex. 2144, 5, 9–11). For example, Dr. Grabowski states that "[o]ne study found that, with respect to injection force, 'SoloSTAR® was preferred by a significantly greater number of patients as their first choice (65%) compared with other pens assessed,' including Novolog® FlexPen® and Lilly's disposable pen." Ex. 2109 ¶ 53 (citing Ex. 2126, 1159). The study Dr. Grabowski cites, however, characterizes its finding as "[r]egarding injection performance," not "injection force" as indicated By Dr. Grabowski, who does not otherwise explain whether the terms are coextensive or whether "injection performance" includes features other than "injection force." Dr. Grabowski also states that another study "compared the injection force of the SoloSTAR® pen to competitor pens" and "concluded that 'SoloSTAR® stands out because of its low injection force, even when compared with newer insulin pen devices such as the KwikPen and NGFP [Next Generation FlexPen®].'" *Id.* (citing Ex. 2100, 150). The study relied upon by Dr. Grabowski was limited to "Other Disposable Insulin Pen Devices" and

states that it was authored by "an employee of sanofi-aventis" and acknowledges that "[e]ditorial support was provided by Global Publications group of sanofi-aventis." Ex. 2100, 150, 155.

Petitioner argues that, in contrast to the "Sanofi-sponsored injection-force studies" relied upon by Patent Owner (*e.g.*, Ex. 2143; Ex. 2144; Ex. 2100; Ex. 2126; Ex. 2116; Ex. 2123), other studies found that SoloSTAR® did not have a lower injection force. Pet. Reply 26 (citing Ex. 2145, 15 (the "US Lantus SoloSTAR Launch Book," stating in regard to SoloSTAR® that "'*[e]asier to inject*' was not supported by two studies showing data versus FlexPen® and Lilly pen"). Dr. Biggs also raised issues with the methodology of at least some of the studies relied on by Patent Owner. Ex. 1048 ¶ 58 n.3.

With regard to Dr. Slocum's opinion that SoloSTAR® provided "a shorter dial extension," "has a maximum of 80 units, while the FlexPen® only has a maximum of 60 units," and has a dial that "would extend to 25.5mm to inject 60 units, [whereas] the FlexPen® must extend to 33mm to inject 60 units," we find insufficient evidence to show that any of these purported features provided a benefit over prior art pen injectors that satisfied any purported long-felt need. *See* Ex. 2107 ¶ 650. Dr. Biggs characterizes any difference between the maximum extension of SoloSTAR® compared to FlexPen® as "difficult to discern visually" and "too slight to be of practical consequence." *Id.* ¶ 55.

We further find unpersuasive Patent Owner's argument that "[t]he industry extensively recognized SoloSTAR[®] for solving the problem of needing to deliver high doses with a short dial extension and with low injection force." PO Resp. 73. As support, Patent Owner relies not on an industry publication, but on a study "supported by Sanofi-Aventis" that

received "[e]ditorial support" from "Global Publications group of Sanofi-Aventis." Ex. 2128, 121. Under the heading "Unmet needs," the study states that "many patients need to administer doses of insulin exceeding 60 units, the maximum dose of many insulin pens." *Id.* at 115. Dr. Biggs explains that there was "no unmet need in 2003 for an 80U pen" because "the Disetronic pen offered this feature years earlier." *Id.* (citing Ex. 1046, 82–83). We agree. We have considered all of the additional "industry" recognition cited by Patent Owner, including Exhibit 2123 (a study funded by Sanofi that found that, when compared to a limited set of certain other pens, Lantus® pens, ClikSTAR® and SoloSTAR®, "require a significantly lower injection force compared with the reusable or prefilled insulin pens containing the insulin glargine copies") and Exhibit 2184 (an article from the "Philippine Daily Inquirer" stating "the Lantus® SoloSTAR® operates with a low injection force?31 [sic] percent less than other insulin pens ?that [sic] allows a gentle injection.").[10] PO Resp. 73. Patent Owner also cites Exhibit 2185 as reflecting a statement from a Professor of Endocrinology in France that "[i]nsulin injection with SoloSTAR® brings flexibility, satisfaction for the patients, and an opportunity for earlier initiation of insulin therapy which may contribute to better long term glycemic control." *Id.* Patent Owner fails to explain how that statement supports the contention that SoloSTAR® satisfied any long-felt, unmet need. The same applies to Patent Owner's purported evidence of patient preferences. *Id.* at 74 (citing Ex. 2121, 2, 9; Ex. 2143; Ex. 2144).

[10] Patent Owner alters the statement from what appears in Exhibit 2184 and also attributes it to a particular individual, however, the article does not make clear from whom the information is coming. *Compare* PO Resp. 73, *with* Ex. 2184, 2.

We have further considered and find unpersuasive all of Patent Owner's additional arguments, including that SoloSTAR® was preferred over OptiClik, that earlier FlexPens were hard to push, that some patients did not take their insulin because prior art devices were problematic, and that patients were transitioned to SoloSTAR® because of its lower injection force. PO Sur-reply 27 (citing Ex. 1056, 34:3–17, 35:7–12; 66:9–15; Ex. 2100; Ex. 2111 ¶¶ 31–43; Ex. 2113; Ex. 2116; Ex. 2121; Ex. 2123; Ex. 2126; Ex. 2128; Ex. 2140; Ex. 2143; Ex. 2144; Ex. 2184; Ex. 2185). Patent Owner also argues that Mr. Leinsing acknowledges a focus on reducing injection force (*id.* (citing Ex. 2316, 80:24–81:1)); that patients would have disliked Dr. Biggs's suggestion that "any long-felt need was satisfied by the Lantus® vial and syringe, that patients complaining of injection force could have caregivers . . . administer their treatments, and that patients could carry around . . . preloaded syringes" (*id.* (citing Ex. 1048 ¶¶ 31–32; Ex. 1056, 52:23–53:25, 58:18–59:24; Ex. 2317, 70:10–19, 84:24–85:14)), and that Dr. Biggs's testimony is undermined by his admission that his suggestions may not be covered under Medicare or insurance and that the majority of his patients switched from Lantus® vial to Lantus® SoloSTAR®, which most patients preferred (*id.* at 28 (citing Ex. 2317, 38:7–39:3, 115:23–116:6, 118:19–22)).

Based on the entirety of the evidence provided by both parties, we conclude for the reasons above that the evidence does not support Patent Owner's argument that SoloSTAR® satisfied a long-felt but unmet need for a pen with "a low injection force," because there were other injection pens that operated with similar and even lower injection forces then SoloSTAR®. Likewise, Patent Owner does not show persuasively that the dial extension or maximum dosing of SoloSTAR® exceeded any other injection pen

available when it was introduced or at the time of the invention of the '486 patent to support the contention that it satisfied a long-felt, but unmet, need.

4. Industry Praise

Patent Owner contends that it received a "high level of praise and industry recognition" for designs in the SoloSTAR device. PO Resp. 74–75. Specifically, Patent Owner directs our attention to evidence indicating that "SoloSTAR won the Gold, International Export, and Grand Prix awards at the Design Business Association (DBA) Design Effectiveness Awards" in 2009. *Id.* at 74 (citing Ex. 2121). According to Patent Owner, "[t]he DBA is a design organization based in the UK that is interested in how a design commercially impacts a company's business." *Id.* Patent Owner asserts that "[t]he case study of SoloSTAR for the DBA Awards describes the SoloSTAR's inventiveness as 'suitably ambitious' and explains that 'SoloSTAR® is the first disposable insulin pen to combine very low injection force (which provides a smooth injection experience for patients) with 80 units maximum dose capability, an important breakthrough.'" PO Resp. 74–75 (citing Ex. 2121, 3).

Patent Owner submits further that "SoloSTAR also won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design." *Id.* at 75 (citing Ex. 2109 ¶ 73). According to Patent Owner, "[i]n connection with this award, the Lantus® and Apidra® SoloSTAR® devices were put into the permanent Design Collection of the Chicago Athenaeum Museum of Architecture and Design, as recognition of its inventiveness." *Id.* (citing Ex. 2109 ¶ 73); *see also* Ex. 2109 ¶ 56 (testifying that Apidra® SoloSTAR® is another product practicing the patent at issue). Patent Owner also submits that "at the Prix Galien USA 2009 Award, which 'recognize[s] innovative biopharmaceutical drugs and medical technologies' and 'is

considered the industry's highest accolade for pharmaceutical research and development — equivalent to the Nobel Prize,' Sanofi and DCA were both finalists." PO Resp. 75 (citing Ex. 2109 ¶ 74); *see also id.* at 74 (identifying DCA as "the design firm with whom Sanofi partnered in creating SoloSTAR®").

Petitioner replies that Patent Owner's evidence is either self-praise or is praise directed to features, such as low injection force, that are not required by the challenged claim. Pet. Reply 27 (citing Ex. 1048 ¶¶ 57–58; Ex. 1055, 79:6–81:19; Ex. 1075). Patent Owner replies that it did not make up or give itself industry praise. PO Sur-reply 28. Patent Owner argues that the awards cannot be disputed. *Id.* (citing Ex. 1060 ¶¶ 57–60). Patent Owner also argues that articles concerning SoloSTAR were peer reviewed, are not diminished by Patent Owner's involvement, and refer to low injection force. *Id.* (citing Ex. 2116; Ex. 2224 (medical journal submission instructions and guidelines); Ex. 2318, 72:11–73:18, 76:2–77:4; Ex. 2223 (GOOD DESIGN Award announcement)).

The only evidence of actual industry praise offered by Patent Owner in this regard is Dr. Grabowski's statement that "[i]n 2009, at the Design Business Association ("DBA") Design Effectiveness Awards, Sanofi won the Gold, International Export, and Grand Prix awards." Ex. 2109 ¶ 72. Dr. Grabowski fails to offer any explanation or evidence to show what these awards mean, how they were awarded, or why they were awarded for SoloSTAR®. Dr. Grabowski instead refers back to the case study prepared by Patent Owner and DCA, Exhibit 2121. *Id.* We find that Exhibit 2121 does not constitute "industry praise" because it was prepared by Patent Owner and DCA and does not reflect the opinion of the industry or even the receipt of praise. Nor can we reach any conclusion about the "Design

Effectiveness Awards" Dr. Grabowski states were given for Solostar® in the absence of any evidence explaining what any of the awards entail.

Second, Patent Owner states that "SoloSTAR also won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design." PO Resp. 75 (citing Ex. 2201). According to Dr. Grabowski, "[t]he criteria for this award are 'quality design of the highest form, function, and aesthetics a standard beyond ordinary consumer products and graphics.'" Ex. 2109 ¶ 73 (purporting to quote a website affiliated with The Chicago Athenaeum Museum of Architecture and Design). Dr. Grabowski also states that "Christian K. Narkiewicz-Laine, President of the Chicago Athenaeum Museum of Architecture and Design noted that 'SoloSTAR® represents a design for social good and for humanitarian concerns.'" *Id.* Petitioner correctly argues that Exhibit 2201, upon which Patent Owner relies, does not attribute any award to "inventiveness," and we further note that Exhibit 2201 provides no explanation for how or why an award was given to SoloSTAR®. *See* Pet. Reply 27.

Dr. Grabowski also states that "the Lantus® and Apidra® SoloSTAR® devices were put into the permanent Design Collection of the Chicago Athenaeum Museum of Architecture and Design, as recognition of its inventiveness." Ex. 2109 ¶ 73. Dr. McDuff explains that the document Dr. Grabowski cites in support of his contention that SoloSTAR® was placed in the above-mentioned Design Collection (*see* Ex. 2109 ¶ 73 n.95) is a DCA press release that does not state that this placement resulted from "recognition of its inventiveness" and contains no statements attributed to the Chicago Athenaeum. Ex. 1060 ¶ 59.

Third, Patent Owner submits that "at the Prix Galien USA 2009 Award, which 'recognize[s] innovative biopharmaceutical drugs and

medical technologies' and 'is considered the industry's highest accolade for pharmaceutical research and development — equivalent to the Nobel Prize,' Sanofi and DCA were both finalists." PO Resp. 64 (citing Ex. 2109 ¶ 74). Patent Owner offers no further explanation of how this constitutes industry praise, but asserts without citation that "Patent Owner did not make up the SoloSTAR® awards or bestow upon itself industry praise." PO Sur-reply 25.

Patent Owner's evidence of industry praise appears to be directed to SoloSTAR®, and not Lantus® SoloSTAR®. Patent Owner would be entitled to a presumption of nexus if Patent Owner shows that SoloSTAR® "embodies the claimed features, and is coextensive with them." *Fox Factory*, 944 F.3d at 1373 (internal quotations omitted). Patent Owner, however, does not show sufficiently that SoloSTAR® practices the challenged claims. Patent Owner does not argue SoloSTAR® is coextensive with any of the challenged claims. For example, the case study of SoloSTAR® Patent Owner relies upon to show industry praise states that an "important breakthrough" was the combination of "very low injection force . . . with 80 units maximum dose capability." Ex. 2121, 3; *see also id.* at 5 (emphasizing the attention given to "visual design" during the development of SoloSTAR® and asserting that it provides "a total of five differentiation features for improved safety: body colour, dial colour, button colour, label design and a tactile feature on the injection button"). None of the challenged claims requires any maximum dose capability or "differentiation features." As with the proffered evidence of long-felt need discussed above, Patent Owner does not demonstrate nexus between the purported evidence of industry praise and the claims at issue in this proceeding.

Moreover, even if we assume Patent Owner demonstrates nexus between the alleged industry praise and the claims at issue, much of the praise was generated by DCA, Sanofi's affiliate. *See, e.g.*, Ex. 1055, 76–79. Such self-generated praise is not persuasive industry praise. Further, evidence independent of DCA, such as consideration of Lantus® SoloSTAR® for the Prix Galien USA 2009 award, only generally specifies the criteria used to judge the nominees. Ex. 2042, 2. It does not evidence industry praise of any specific feature of the claimed invention. *Id.*

5. Commercial Success

Patent Owner contends that SoloSTAR contributed to "the growth of the LANTUS® franchise overall" and performed well "compared to other long-acting insulin and insulin analog pens." PO Resp. 76.

a) Patent Owner Fails to Show a Nexus Between the Purported Evidence of Commercial Success and Any Challenged Claim of the '486 Patent

First, Patent Owner fails to show that the asserted evidence of commercial success of Lantus® SoloSTAR is a "direct result of the unique characteristics of the claimed invention," and, therefore, fails to show the necessary nexus. *Fox Factory*, 944 F.3d at 1373–74 (internal quotation omitted). Patent Owner argues that "each of the features of the device disclosed and claimed in the 486 Patent and used in Lantus® SoloSTAR® contributed to its commercial success." PO Resp. 77 (citing Ex. 2109 ¶ 53; Ex. 2107 ¶¶ 513–550, 650); *see also* PO Sur-reply 25 (asserting that the commercial success of Lantus® SoloSTAR® "is due at least in part to the elegant features that the challenged claims enable, such as low injection force"). Specifically, Patent Owner argues that SoloSTAR® satisfied a long-felt but unfulfilled need for an easy-to-use pen device with low injection

force. *Id.*; *see also id.* at 80 (arguing that "[t]he tremendous success of Lantus® SoloSTAR®, as compared to pens with long-acting insulins that failed to address the long-felt but unfilled need for a low injection force device, therefore shares a strong nexus with the claimed invention").

Patent Owner does not show that the alleged "tremendous success" may fairly be attributed to the claimed invention, which does not require low injection force or insulin, let alone the long-acting insulin formulation of Lantus. Patent Owner's argument does not show the necessary nexus, and for the reasons provided above, we found no persuasive evidence in support of Patent Owner's allegations of long felt need. We likewise find unpersuasive Patent Owner's argument that, because OptiClik® also dispensed Lantus, but had a "higher injection force" and "performed significantly worse than SoloSTAR®" such that it was discontinued, the "nexus between SoloSTAR®'s lower injection force and its commercial success is further confirmed." PO Sur-reply 25 (citing Ex. 2109 ¶¶ 19, 35–30; Ex. 2111 ¶ 28). While the parties appear to agree that the OptiClik® was an inferior device, Patent Owner's implication that it was discontinued only due to its higher injection force is not even supported by Patent Owner's own expert, Dr. Goland, who explained that "Lantus® OptiClik® was thus a mechanically inferior design to Lantus® SoloSTAR®" because, in addition to a higher injection force, OptiClik® "did not automatically reset after injection and thus required additional steps by the user prior to its next," and "was also relatively large, making it less convenient to carry." Ex. 2111 ¶ 28. Dr. Biggs described OptiClik® as "difficult to refill and unreliable about delivering accurate doses" (citing Ex. 1045, 528, Table 2), and a "truly bad pen," but noted that "injection force" was not a concern with OptiClik® expressed by his patients. Ex. 1048 ¶¶ 42, 49.

Next Patent Owner asserts that "the SoloSTAR® device won numerous design awards, and achieved significant industry praise." PO Resp. 78. Again, Patent Owner's argument does not show the necessary nexus, and for the reasons provided above, we found no persuasive evidence in support of Patent Owner's allegations of industry praise. The only remaining arguments Patent Owner makes is that "the SoloSTAR® device embodies the challenged claims of the 486 patent," and "[t]hus, there is a nexus between the claimed invention in the 486 patent and the commercial success of Lantus® SoloSTAR®." *Id.* Patent Owner is wrong with regard to what must be shown to establish nexus.

There is no dispute that Lantus® SoloSTAR® is not coextensive with any of the challenged claims. Patent Owner relies on Lantus® SoloSTAR® to show commercial success, but merely showing that SoloSTAR® "embodies" any of the challenged claims fails to establish the necessary nexus between the evidence of commercial success and any claim challenged. Patent Owner suggests that "the success of SoloSTAR® is attributable at least in part to its unique design covered by the 486 patent." PO Resp. 80. Contrary to Patent Owner's argument, Patent Owner does not show persuasively that any "feature" purportedly disclosed and claimed in the '486 patent contributed to the commercial success of Lantus® SoloSTAR®. To be clear, that does not mean that the design of SoloSTAR®, including unclaimed features and aesthetics, was irrelevant to the purported commercial success of Lantus® SoloSTAR®. Rather, Patent Owner does not show that the asserted evidence of commercial success of Lantus® SoloSTAR is a "direct result of the unique characteristics of the claimed invention."

b) Patent Owner Fails to Show Commercial Success of Lantus® SoloSTAR®

Patent Owner argues that the following demonstrate the commercial success Lantus® SoloSTAR®:

- "fast and long-sustained growth in terms of dollar sales, new prescriptions, and total prescriptions";
- "the overall levels and shares of dollar sales, new prescriptions, and total prescriptions, as well as the profitability and formulary placement";
- "sales and prescriptions . . . remained strong despite the entry of several competing long-acting insulin and insulin analog drugs (all in pen form) starting in 2015";
- "the highest level of sales among long-acting insulin and insulin analog pens even though it launched after several other long-acting insulin and insulin analog pens, including the Levemir® FlexPen®"; and
- "substantial growth relative to Lantus® OptiClik®" based on new prescriptions and total prescriptions.

PO Resp. 76–77 (citing Ex. 2109 ¶¶ 12, 37). Additionally, Patent Owner contends that marketing does not explain the commercial success because "marketing expenditures for Lantus® SoloSTAR® were in line with, or were lower than, many other long-acting insulin products." *Id.* at 79 (citing Ex. 2109 ¶¶ 16, 64–69). Regarding "alleged 'blocking patents' covering the glargine molecule that is used in the production of the active ingredient in Lantus®," Patent Owner argues that "the law does not mandate across-the-board-discounting of commercial success simply because other patents cover components of the product," and that the Board should "weigh the evidence

on a case-by-case basis, in light of the specific commercial success argument being made." *Id.* According to Patent Owner, "the success of Lantus® SoloSTAR® cannot be attributed solely to the insulin glargine molecule because Lantus® OptiClik® used the exact same Lantus® formulation" and did not achieve SoloSTAR®'s success, thus the design of SoloSTAR® must have attributed at least in part to the success. *Id.* at 80. Patent Owner further argues that "Sanofi's earlier patents on the insulin glargine molecule did not prevent others from entering the market for non-glargine, long-acting insulin products and competing with Lantus® SoloSTAR®." *Id.* Patent Owner identifies Levemir® FlexPen® with its long-acting insulin as an example of a disposable pen device with long-acting insulin. *Id.*

Petitioner disputes Patent Owner's contentions, arguing, *inter alia*, that Patent Owner does not address profitability and "provides no benchmarks for evaluating success, applies a faulty 'pens-only' market definition, and [that] formulary status does not separately demonstrate commercial success." Pet. Reply 27–28 (citing Ex. 1048 ¶¶ 17–28). Petitioner also argues that "Lantus® SoloSTAR® enjoyed the benefit of a Lantus® franchise that predated the Levemir® franchise by five years and the foundation of earlier Lantus® pen (OptiClik®)," which had "twice as many prescriptions in 2007 as Levemir® FlexPen®." *Id.* at 28 (citing Ex. 2186, 2; Ex. 2198). Petitioner contends that "Lantus® SoloSTAR® overtook Levemir® FlexPen® not because of any unique SoloSTAR® attributes," but because Patent Owner "selected it as the exclusive Lantus® pen in the United States." *Id.* (citing Ex. 1048 ¶¶ 20–22, 30–35).

Patent Owner replies that Petitioner's own data shows that Lantus® SoloSTAR® has been commercially successful (citing Ex. 1060, Attachment B-10; Ex. 2318, 31:14–17, 31:25–32:8), that the diabetes

community has widely adopted Lantus® SoloSTAR®; that Dr. McDuff acknowledged the large Lantus® SoloSTAR® sales and admitted that profitability analysis is not required (citing Ex. 2318, 15:10–13, 28:7–19, 29:20–30:18), and that Lantus® SoloSTAR® has the largest market share in Petitioner's asserted broader market (citing Ex. 1060, Attachment B-10; Ex. 2318, 31:14–17, 31:25–32:8). PO Sur-reply 22–23. Patent Owner further contends that Lantus® SoloSTAR® prescriptions more than quadrupled that of OptiClik® in the first four years of each product's respective launch and that Lantus® SoloSTAR® grew the Lantus® market and remains the number one product. *Id.* at 23 (citing Ex. 1060, Attachment B-10; Ex. 2318, 18:23–19:20, 21:22–22:8). Patent Owner asserts that "SoloSTAR® enjoys favorable placement in health," due, in part as admitted by Dr. McDuff, to its "mechanical features and attributes." *Id.* at 23–24 (citing Ex. 2318, 33:7–36:3).

Having considered all of the evidence of commercial success presented by the parties, we find that the data presented in Attachment B-10 of Exhibit 1060 to be the most pertinent evidence regarding the purported commercial success of Lantus® SoloSTAR® provided in this proceeding. Attachment B-10 presents total prescription data by year for 40 insulin delivery products for the 20-year period 1999–2019. Ex. 1060, Attachment B-10. It also provides corresponding market share data for that same time period. *Id.*

Attachment B-10 shows that from the introduction of Lantus® Vial in 2002, until 2019, Lantus® delivery products (i.e., Lantus® Vial, Lantus® OptiClik®, and Lantus® SoloSTAR®) were by far the most proscribed insulin delivery devices. Ex. 1060, Attachment B-10. As shown, from 2002 to 2011 prescriptions of Lantus® Vial grew from roughly 1.3 to 11 million

prescriptions, while the most successful competing products (Humulin and Novolog) each grew to prescription levels of roughly 5 million prescriptions. *Id.* Thus, Attachment B-10 clearly demonstrates the commercial success of Lantus® Vial during that time period. Attachment B-10 also demonstrates that once Lantus® OptiClik® was introduced, prescriptions of Lantus® Vial decreased as prescriptions of Lantus® OptiClik® increased, with the overall number of Lantus® OptiClik® prescriptions slowly, but steadily climbing. *Id.* We note that during the time period that Lantus® OptiClik® was the only Lantus® alternative to Lantus® Vial, the number of Lantus® Vial prescriptions essentially stayed the same.

In 2008, Lantus® SoloSTAR® was introduced. Ex. 1060, Attachment B-10. From 2008–2011, prescriptions of Lantus® SoloSTAR® steadily rose while prescriptions of Lantus® OptiClik® declined. *Id.* During this time period, prescriptions of Lantus® Vial continued to remain steady. *Id.* Then in 2012, things changed. *Id.* First, prescriptions of Lantus® OptiClik® dropped off significantly. *Id.* By 2014, prescriptions of Lantus® OptiClik® dropped to a mere 382 prescriptions. *Id.* During the time period from 2011–2016 (when prescriptions of Lantus® SoloSTAR® hit their peak), prescriptions of Lantus® Vial began to decrease at a rate of about 500,000 prescriptions per year. It is unknown why prescriptions of Lantus® Vial began to decline starting in 2012, but it appears that they declined as the prescriptions of Lantus® SoloSTAR® increased. Regardless of the reason for the decline, the evidence clearly shows that the number of Lantus® SoloSTAR® prescriptions peaked in 2016 and that most of the increase in prescriptions for Lantus® SoloSTAR® merely offset the decline in prescriptions for Lantus® Vial. Thus, the evidence does not support a showing of commercial success for Lantus® SoloSTAR®. Rather, it appears

to show a fairly stable number of prescriptions for Lantus® products from 2009–2016, with a decline in those prescriptions from 2017–2019.

6. Determination as to Indicia of Nonobviousness

Having considered all the indicia of nonobviousness submitted by Patent Owner, we do not find sufficient evidence of nexus to long-felt need, industry praise, or commercial success.

G. Weighing the Graham *Factors*

"Once all relevant facts are found, the ultimate legal determination [of obviousness] involves weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan." *Arctic Cat*, 876 F.3d at 1361. Above, based on full record before us, we provide our factual findings regarding (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) any differences between the claimed subject matter and the prior art, and (4) objective evidence of nonobviousness.

In particular, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record; (2) Steenfeldt-Jensen teaches or suggests each of the limitations of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40; (3) one of ordinary skill in the art would have had a reason to modify Steenfeldt-Jensen with a reasonable expectation of success, and (4) there is insufficient demonstration of nexus to objective evidence of nonobviousness in the record.

Having considered all the evidence of indicia of nonobviousness, Patent Owner does not show the requisite nexus between the alleged objective indicia of nonobviousness and claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the '486 patent. Moreover, even if Patent Owner had shown nexus, the objective evidence of nonobviousness identified by

Patent Owner fails to show persuasive evidence of a long-felt, unmet need satisfied by the invention of any of the challenged claims. Patent Owner also fails to show persuasive evidence of either industry praise of SoloSTAR® or of commercial success of Lantus® SoloSTAR®. Thus, Patent Owner's evidence of indicia of nonobviousness provides very little, if any, support for nonobviousness of the challenged claims.

Weighing these findings, a preponderance of the evidence persuades us that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the '486 patent are unpatentable over Steenfeldt-Jensen.

H. Remaining Challenge

Petitioner also challenges claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 as unpatentable over Moller and Steenfeldt-Jensen. Pet. 57–98. Because we determine that the same claims are unpatentable over Steenfeldt-Jensen alone, we do not reach this additional challenge. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged").

III. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Exhibits 1054, 2001–2023, 2100–2107, 2109, 2113–2115, 2117–2120, 2122, 2124, 2125, 2129–2135, 2138–2141, 2145–2153, 2158–2162, 2167–2174, 2176–2183, 2186–2200, 2203–2212, 2214–2218, and 2223–2225. Mot. 1. Petitioner notes that objections were filed. *Id.* (citing Papers 22, 33, 57). Petitioner, as the "moving party," "has the burden of proof to establish that it is entitled to the requested relief." 37 C.F.R. § 42.20(c).

A. Exhibits 2001–2010 and 2016–2023

Petitioner moves to exclude Exhibits 2001–2010 pursuant to Federal Rules of Evidence ("FRE") 402 and 403 because purportedly they are not relevant to any contested issue in this proceeding and risk confusing the issues. Mot. 1–2, 4–5. Patent Owner responds that these exhibits "were offered to show information that was relevant to § 325(d) issues raised during the preliminary stage of this proceeding." Opp. 1. Patent Owner asserts that these exhibits do not lack relevance, have no risk of confusing the issues, and should therefore remain in the record. *Id.* In its Motion Reply, Petitioner contends that Patent Owner acknowledges that these exhibits no longer have relevance to the issues in this proceeding and should therefore be excluded. Mot. Reply 1. Petitioner asserts that if not excluded, "their admissibility should be limited to the purpose for which they were submitted" pursuant to FRE 105. *Id.*

Petitioner's only basis to exclude these exhibits is because they were offered during the pre-institution phase of this proceeding concerning only our discretion to deny institution, not the merits of the asserted grounds of unpatentability, and are therefore no longer relevant. Petitioner does not direct our attention to any prior Board decision that granted a motion to exclude exhibits that were relevant only to the pre-institution phase of an *inter partes* review. And, we do not agree that we should do so here. In an *inter partes* review, which is akin to a bench trial, there is little risk of confusion. Additionally, simply because an exhibit is relevant to the pre-institution stage and not necessarily the post-institution stage of an *inter partes* review proceeding, does not justify excluding it from the record. To the contrary, the record contains other documents that may similarly be characterized as such, e.g., a patent owner's preliminary response.

Therefore, we are not persuaded to exclude the exhibits or expressly limit their purpose pursuant to FRE 105 and Petitioner's Motion is denied with respect to these exhibits.

B. Exhibit 2011

Exhibit 2011 is an animation purportedly showing the operation of an embodiment of the injection pen described in the '486 patent. Mot. 3. Petitioner contends that Exhibit 2011 should be excluded under FRE 801–804 as hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions. *Id.*

Patent Owner contends that FRE 703 permits experts to rely upon hearsay if reasonable to do so in the expert's field. Opp. 1. Patent Owner asserts that Exhibit 2011 is identical to Exhibit 2117, which Dr. Slocum relies upon in his declaration. *Id.* (citing Ex. 2107 ¶ 65). Patent Owner asserts that "[c]omputer models such as shown in EX2011 are used and relied upon in mechanical engineering" and because it was reasonable for Dr. Slocum to rely upon it for his analysis, it should not be excluded. *Id.* at 1–2.

In its Motion Reply, Petitioner contends that although an expert may rely upon hearsay in forming an opinion, pursuant to FRE 703, that does not make the evidence admissible in trial. Mot. Reply 2. Petitioner asserts that if the exhibit is not excluded, it should be limited to the purpose for which it was submitted—showing the basis for Dr. Slocum's expert testimony—and should not be used for any other purpose. *Id.* (citing FRE 105).

Patent Owner does not dispute that Exhibit 2011 constitutes hearsay. Petitioner does not dispute that Dr. Slocum was permitted to rely upon it in formulating his opinions. Patent Owner does not contend that Dr. Slocum relied upon Exhibit 2011; rather, Patent Owner asserts Dr. Slocum relied

upon Exhibit 2117, which Patent Owner asserts is identical to Exhibit 2011. Patent Owner does not explain why it submitted two identical animations as exhibits or why it needs both Exhibit 2011 and Exhibit 2117 in the record when Dr. Slocum opined regarding Exhibit 2117. Nonetheless, to the extent Exhibit 2011 was cited during this proceeding, we do not wish to disturb the record by excluding it as a duplicate. Accordingly, although Petitioner's Motion is denied, we agree that the use of Exhibit 2011 should be, and hereby is, limited to the purpose of showing the basis for Dr. Slocum's testimony.

C. Exhibits 2012 and 2013

Exhibits 2012 is Mylan's construction brief in related litigation, and Exhibit 2013 is a district court's interpretations. Petitioner argues that these exhibits should be excluded under FRE 402 and 403 because they lack relevant, risk confusing the issues, and are prejudicial. Mot. 3. Patent Owner responds that Exhibit 2012 "was offered to show that . . . Mylan agreed that the same claim term used in related patents having different specifications should be given the same construction," "does not lack relevance," and "should remain in the record." Opp. 2. Patent Owner also responds that Exhibit 2013 "is probative of the construction that should be applied in this proceeding" and has been considered in the institution decision without any confusion. *Id.* (citing Dec. to Inst. 15). Petitioner provides the same reply that it did for Exhibits 2001–2010 and 2016–2023 discussed above. Mot. Reply 1–2 (arguing reliance does not mean the exhibit is admissible and if not excluded, the exhibit should be limited to the purpose for which it was submitted).

Petitioner does not carry its burden of showing why Exhibits 2012 and 2013 should be excluded. We agree with Patent Owner that Exhibits 2012

and 2013 are relevant to and probative of claim interpretation and do not risk confusion. Petitioner's Motion is denied with respect to these exhibits.

D. Exhibit 2015

Exhibit 2015 is an animation purportedly showing the operation of an embodiment of the injection pen described in Moller. Mot. 4. Petitioner contends that they should be excluded under FRE 801–804 as hearsay because they are offered for the truth of their content without satisfying any of the hearsay exceptions. *Id.* Patent Owner contends that FRE 703 permits experts to rely upon hearsay if reasonable to do so in the expert's field. Opp. 3. Patent Owner also contends that Dr. Slocum reasonably relied upon these exhibits, similar animations "are used and relied upon in mechanical engineering," and thus, they should not be excluded. *Id.* (citing Ex. 1053, 34:8–36:19; Ex. 2107 ¶ 150). Petitioner provides the same reply that it did for Exhibit 2011 discussed above. Mot. Reply 1–2 (arguing reliance does not mean the exhibit is admissible and if not excluded, the exhibit should be limited to the purpose for which it was submitted).

For reasons similar to the ones discussed for Exhibit 2011, although Petitioner's Motion is denied, we agree that the use of Exhibit 2015 should be, and hereby is, limited to the purpose of showing the basis for Dr. Slocum's testimony.

E. Exhibits 1054 and 2107

Petitioner seeks to exclude Dr. Slocum's entire declaration (Ex. 2107) and the deposition redirect examination of Dr. Slocum (Ex. 1054, 391–406) pursuant to FRE 702, 703, and 705. Mot. 5–8. Petitioner raises three primary reasons. First, that Dr. Slocum did not have personal knowledge of injection pens or the industry during the relevant time period. *Id.* at 5. Second, that Dr. Slocum relied upon Mr. Veasey, one of the named

inventors of the ’044 patent, for certain data and a model used for various calculations in Dr. Slocum’s declaration. *Id.* at 5–7. And, third, that Exhibit 2017 should be excluded for the additional reason that it “does not provide sufficient facts or data, is not the product of reliable principles and methods, and has not applied the proper principles to the facts of this proceeding.” *Id.* at 7. As an example, Petitioner contends that Appendices A through F “do not set forth the principles used nor do they demonstrate the calculations used in generating the spreadsheets” and, thus, “should be excluded for failing to disclose the underlying facts and data, and failing to set forth the bases of Dr. Slocum’s opinions.” *Id.* at 8.

Patent Owner responds to each of Petitioner’s challenges. First, with respect to Dr. Slocum’s personal knowledge, Patent Owner correctly observes that neither party’s proposed definition of the ordinary level of skill in the art requires specific knowledge of, or experience with, pen injectors. Opp. 3–4. Additionally, Patent Owner contends that there is no requirement that an expert have personal knowledge of the subject matter upon which the expert’s opinion is based at the time of the invention. Opp. 4. Further, Patent Owner asserts that Dr. Slocum acquired the relevant knowledge by “(i) research[ing] the prior art, (ii) canvass[ing] literature on pre-critical date pen injectors, design considerations, and design standards, and (iii) convers[ing] with those in the industry (*i.e.*, Mr. Veasey and Dr. Goland).” *Id.* at 7 (citing Ex. 2107 ¶¶ 25–61). Patent Owner also contends Dr. Slocum documented his opinions with facts and data. *Id.*

Second, Patent Owner asserts that Petitioner’s criticism of Dr. Slocum’s reliance upon the information and model obtained from Mr. Veasey are unfounded. In particular, Patent Owner asserts that Dr. Slocum performed his own investigation and research into design

considerations and the state of the art, as documented in his declaration. *Id.* at 8–9 (citing Ex. 2107 ¶¶ 25–61). Patent Owner raises additional arguments regarding the specific discussions between Dr. Slocum and Mr. Veasey. *Id.* at 8–10 (discussing measurements of the FlexPen and embodiments in Steenfeldt-Jensen). Patent Owner notes that Petitioner does not assert that any of the design considerations noted by Dr. Slocum are incorrect. *Id.* at 9.

Third, Patent Owner contends that Petitioner ignores that Patent Owner "served as supplement[al] evidence the native spreadsheets that specify [the] principles and calculations" set forth in Appendices A through F. *Id.* at 11 (citing Ex. 2226). Patent Owner further asserts that "the measurements provided by Mr. Veasey are corroborated, unrebutted, and reliable." *Id.*

Petitioner's Motion Reply reiterates Petitioner's contentions regarding Dr. Slocum, including that even if he could be an expert, he "objectively failed to act as an expert in this case." Mot. Reply 2. Petitioner also challenges Dr. Slocum's acceptance of Mr. Veasey's data "without question," contending that Dr. Slocum only did so because "he had no relevant knowledge or experience." *Id.* at 3. Petitioner also asserts that Patent Owner hid Mr. Veasey's involvement in Dr. Slocum's testimony precluding Petitioner from cross-examining Mr. Veasey. *Id.*

To begin, Dr. Slocum is undisputedly an expert in mechanical engineering with knowledge and experience *beyond* the level of ordinary skill in the art as the parties have proposed and we have adopted. *See Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008) (noting that "[a] witness possessing merely ordinary skill will often be qualified to present expert testimony both in patent trials and more generally"). Additionally, as both parties acknowledge, there is no

requirement that an expert have personal knowledge of the technology during the specific relevant time period in order to qualify as an expert. In this regard, we find that Patent Owner and Dr. Slocum have established sufficient support, as detailed above, as to how he acquired knowledge of the specific technology at issue—the mechanical operation and design of injection pens. Further, Dr. Slocum's reliance upon other individuals, including Mr. Veasey, to provide information upon which he based his opinions does not render him unqualified to offer an expert opinion. To the extent the credibility of any of the individuals upon which Dr. Slocum relied may be in doubt, e.g., Mr. Veasey's potential bias as a named inventor on the '486 patent, those issues are the proper subject of cross-examination, go to the weight accorded the evidence, and do not justify excluding Dr. Slocum's testimony on the facts presented here. And, to the extent Petitioner questions the data or model provided by Mr. Veasey, the proper recourse is to probe the bases for such during cross-examination, as discussed further below. Therefore, Petitioner has not shown that Dr. Slocum should be disqualified as an expert in this proceeding. Accordingly, Petitioner's Motion as directed to the redirect examination testimony of Exhibit 1054 and Dr. Slocum's declaration (Ex. 2107) is denied.

We find that Petitioner's assertions that Patent Owner hid Mr. Veasey's involvement are unfounded. In particular, Dr. Slocum acknowledged in Appendix B of his declaration that the "[i]nput values were provided by Mr. Robert Veasey of DCA Engineering." Ex. 2107, App. B at 2. Thus, we find that Petitioner could have, but did not, seek to depose Mr. Veasey and therefore Petitioner's arguments regarding Mr. Veasey's involvement do not justify excluding Dr. Slocum's declaration (Ex. 2107) or

redirect testimony (Ex. 1054). *See also* Tr. 35:15–36:7 (Petitioner's counsel describing decision not to cross-examine Mr. Veasey), 93:16–25 (Petitioner's counsel acknowledging that Appendix B states Mr. Veasey provided inputs).

F. Exhibits 2100, 2102–2106, 2113–2115, 2118–2120, 2122, 2124, 2125, 2129–2135, 2138–2141, 2145, 2151, 2153, 2158–2161, 2167–2174, 2176–2183, 2186–2200, 2203–2210, 2212, 2214, 2218, and 2225

Petitioner contends the above-listed exhibits should be excluded pursuant to FRE 402 and 403 "because they were not discussed in the response, cannot be relevant to it, and consequently serve only to confuse and create prejudice through belated surprise." Mot. 7. Patent Owner contends that Exhibits 2100–2102 and 2104–2106 are exhibits to the deposition of Mr. Leinsing and are relevant because they "provide necessary context for Mr. Leinsing's cross-examination, which Petitioner has not sought to exclude." Opp. 4. Additionally, Patent Owner asserts that Dr. Slocum "considered and reasonably relied upon [each of these exhibits] in forming his opinions regarding the validity of the challenged patent and thus should be admitted under FRE703." *Id.* Patent Owner also contends that "EX2124, 2145, 2151, 2186–2199, 2203–2205, [and] 2208–2210 were also considered and expressly cited by Dr. Grabowski in forming his opinions" and "EX2125, 2140-2141, and 2200 were also considered and expressly cited by Dr. Goland in forming her opinions." *Id.* at 5 (citing Ex. 2109 ¶¶ 32–34, 39–45, 51, 53–55, 66–68; Ex. 2111 ¶¶ 23, 25, 43). Petitioner does not address these exhibits in its Motion Reply.

Patent Owner filed the same declaration by Dr. Slocum in nine related *inter partes* reviews, including this proceeding. *See* Ex. 2107, caption. We cite these exhibits to indicate where Patent Owner believes support can be

found for its asserted objective indicia of nonobviousness. We do not, however, rely on these exhibits in our analysis. Additionally, the sole basis argued in Petitioner's Motion for exclusion—that the exhibits were not cited in Patent Owner's Response—is not, in and of itself, dispositive as to whether an exhibit should be excluded. Accordingly, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

G. Exhibit 2109

Petitioner contends that Exhibit 2109, the Declaration of Henry G. Grabowski, Ph.D., should be excluded under FRE 702, 703, and 705 "because it does not provide sufficient facts or data, is not the product of reliable principles and methods, and has not applied the proper principles to the facts of this proceeding." Mot. 8. Patent Owner argues that "Petitioner cites no authority that a party must file every single document that an expert considers in forming his opinions" and that Patent Owner has disclosed "Dr. Grabowski's reliance on IMS Health data," "the underlying IMS Health data is voluminous," and "Petitioner independently obtained the IMS Health data and moved it into the public record" of related litigation. Opp. 12–13.

Petitioner also contends that paragraphs 19, 20, 31, 35, 45, 49, 50, 52, 53, 56, 71, and 72 of the exhibit should be excluded under FRE 801–804 "because they constitute hearsay to the extent they repeat and rely on statements made in an interview." Mot. 8. Patent Owner argues that "FRE703 permits experts to rely upon hearsay if reasonable to do so in the expert's field" and Dr. Grabowski, a pharmaceutical economist, reasonably relied on "a device expert (Dr. Slocum) and an endocrinologist (Dr. Goland), both of whom are reliable sources and were subject to cross-examination." Opp. 12. Patent Owner also argues that "Dr. Grabowski does not introduce

the hearsay statements of the two experts; instead, he provides his own opinions of the facts based on his interviews." *Id.*

Petitioner replies that Patent Owner's position is contrary to 37 C.F.R. § 42.65(a) and contradicts Patent Owner's "arguments regarding various hearsay exhibits which [Patent Owner] argues should not be excluded despite their uncontroverted *inadmissibility* because they provide basis for an expert's opinion." Mot. Reply 4.

Whether every supporting document for Exhibit 2109 has been filed in addition to being identified in Dr. Grabowski's declaration, goes to the weight we should give to that testimony. As for the paragraphs at issue from Exhibit 2019, Petitioner deposed Dr. Grabowski (Ex. 1055), Dr. Slocum (Exs. 1053, 1054), and Dr. Goland (Ex. 1056), and we agree with Patent Owner that Dr. Grabowski "provides his own opinions . . . based on his interviews," which we can appropriately weigh. Opp. 12. Thus, Petitioner's motion with respect to Exhibit 2109 is denied.

H. Exhibits 2101, 2116, 2117, 2121, 2123, 2126, 2128, 2136, 2137, 2142–2144, 2175, 2184, 2185, and 2201

Petitioner contends that Exhibits 2101, 2116, 2117, 2121, 2123, 2126, 2128, 2136, 2137, 2142–2144, 2175, 2184, 2185, and 2201 "should be excluded under FRE 402–403" because these exhibits "which relate to commercial pens and their properties, such as injection force, are irrelevant to the extent they rely on an improper standard of obviousness and unclaimed features." Mot. 9.

Patent Owner contends that "the challenged claims enable the low injection force of the SoloSTAR pen, making the device easier to use," "[t]he challenged patents also describe that the invention reduces injection force," and "Petitioner's contention that the challenged claims do not enable

low injection force is no basis to exclude these exhibits on relevancy grounds." Opp. 14 (citing Ex. 1001, 3:44–47; Ex. 2107 ¶ 650). Patent Owner also contends that "Dr. Grabowski is permitted to rely upon these exhibits under FRE703" and thus, "there is no basis to exclude them." *Id.*

Petitioner replies that Patent Owner has not shown that the challenged claim requires the purported advantages so has not shown that these exhibits are relevant. Mot. Reply 5. Petitioner also contends that Patent Owner "has not otherwise contested the inadmissibility of these exhibits, which should be excluded as irrelevant and misleading" and "[i]f not, the exhibits should be limited to the purpose for which they were submitted (showing the benefits of unclaimed features)." *Id.* (citing FRE 105, 402, 403).

Arguments about the scope of the claim and the properties described in these exhibits are not properly related to whether these exhibits should be excluded. We view these arguments as more related to a matter at issue in this proceeding. Petitioner does not dispute that Dr. Grabowski and Dr. Goland were permitted to rely upon some of these exhibits in formulating their opinions.

Accordingly, Petitioner's Motion is denied as to Exhibits 2101, 2116, 2117, 2121, 2123, 2126, 2128, 2136, 2137, 2142–2144, 2175, 2184, 2185, and 2201. The use of these exhibits is limited to showing the basis for Dr. Grabowski's testimony.

I. Exhibits 2117, 2147–2152, 2162, 2167, 2168, 2206, 2207, 2211, and 2215–2218[11]

Petitioner contends the above-listed exhibits are animations "offered to show animated operations of prior art and non-prior art injection pens" and should be excluded pursuant to FRE 801–804 "because they are offered for the truth of their contents without satisfying any of the hearsay exceptions." Mot. 9. Patent Owner provides the same response here as it did with respect to Petitioner's challenge to Exhibit 2011. Opp. 13–14. Namely, Dr. Slocum relied upon each in formulating his opinions. *Id.* Petitioner contends that, if they are not excluded, they should be limited to the purpose for which they were submitted—showing the basis for Dr. Slocum's expert testimony—and not used for any other purpose pursuant to FRE 105. Mot. Reply 5.

For the reasons explained in our discussion of Exhibit 2011, we do not exclude these exhibits, but we do agree with Petitioner that their use shall be limited to showing the basis for Dr. Slocum's testimony.

J. Exhibits 2223 and 2224

Petitioner contends that Exhibits 2223 and 2224 are offered to show objective indicia of nonobviousness, but "[t]hey are hearsay without exception, lack authentication, and are unreasonably prejudicial because they are cited for a new purpose." Mot. 10. Patent Owner contends that these exhibits are relevant to objective indicia of nonobviousness and that Exhibit 2224 pertains to an exhibit cited in declarations by Dr. McDuff and

[11] Petitioner's challenge to the admissibility of these exhibits pursuant to FRE 402 and 403 is discussed above. This section is directed to Petitioner's challenge based on FRE 801–804, which Petitioner discusses separately. *Compare* Mot. 4–6 (addressing FRE 402 and 403), *with id.* at 8 (addressing FRE 801–804).

Dr. Grabowski directed to the same issue. Opp. 14–15. Petitioner does not address Patent Owner's arguments in its Motion Reply.

Patent Owner does not dispute that these exhibits constitute hearsay, and Petitioner does not dispute that Dr. McDuff and Dr. Grabowski were permitted to rely upon an exhibit that pertains to Exhibits 2223 and 2224 in formulating their opinions. Accordingly, Petitioner's Motion is denied as to Exhibits 2223 and 2224, but their use is limited to showing the basis for Dr. McDuff's and Dr. Grabowski's testimonies.

IV. CONCLUSION[12]

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–6, 12–18, 20, 23, 26–30, 32, 33, 36, 38–40	103	Steenfeldt-Jensen	1–6, 12–18, 20, 23, 26–30, 32, 33, 36, 38–40	
1–6, 12–18, 20, 23, 26–30, 32, 33, 36, 38–40	103	Moller, Steenfeldt-Jensen[13]		
Overall Outcome			1–6, 12–18, 20, 23, 26–30, 32, 33, 36, 38–40	

[12] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

[13] As explained above in Section II.H., we do not reach the challenge to claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, 38–40 based on Moller and Steenfeldt-Jensen because the same claims are determined to be unpatentable over Steenfeldt-Jensen.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of U.S. Patent No. 8,992,486 B2 have been shown, by a preponderance of the evidence, to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 64) is denied; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2018-01678
Patent 8,992,486 B2

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